A. Patient Inform	ation								
Patient Identifier	Date of h	oirth	Sex	Weight					
387	11-13-95	5	female	37	lbs				
B. Adverse even	t or prod	uct pı	roblem						
Advers	Adverse Event & Product Problem								
Outcomes attribu	ted to adv	erse e	event						
death	disa	bility							
☐ life-threatening	\Box_{cong}	genital	anomaly						
$\square_{ m hospit}$ alization	\square_{requ}	ired in	ntervention						
other: Dr. visit									
Date of event 09-	15-00	Date	of report	9/18/2	2000				
Describe event or	problem								
Infested with head									
counter shampoos									
It became hard to to It was also hard to				n lice or r	ash.				
it was also hard to	ten n it w	as mus	or scabs.						
Dalamant tartellah	4	-4-							
Relevant tests/lab	oratory d	ata							
Other relevant hi	story, inc	luding	g preexisti	ng condi	tion				

Triage Unit Sequence #	

C. Suspect med	lication(s)					
Name: Nix						
Rid, Clear, Brite-Life						
Dose, frequency, route use The			rapy d	ates		
Used recommende	ed dosages	06-2	2000	to		
twice for each pro	duct			to 09-2000		
Diagnosis for us	e		Event	abated after use		
Kill head lice			stoppe	d or dose reduced		
			yes			
 Lot #	Exp. date			7 0.		
Lot #	Ехр. часс			reappeared after		
			reintro	oduction		
NDC# -	_		yes			
Concomitant me	dical produ	rts				
Concomitant me	uicai prouu	LLS				
	· · · · · · · · · · · · · · · · · · ·					
D. Suspect med	dical device	•				
Brand name						
Type of device						
Manufacturer na	ame and add	lress		ator of device		
				ealth professional		
user facility						
			\sqcup_d	istributor		
			Expi	ration date		
model #						
catalog #			If im	planted, give date		
serial #						
lot #			If exp	olanted, give date		
other #	·					
Device available						
yes \square_{no}				urer/_/		
Concomitant me	uicai produ	LLS				
E. Reporter						
Name and addre	ss	p	hone #	(781)449-6487		
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
Health professio	nal Occup	oatio	n	Also reported to		
$\mathbf{V}_{\mathrm{yes}}$ \square_{no})			manufacturer		
If you do NOT want your identity user facility						
disclosed to the manufacturer, place an distributor						

A. Patient Inform	ation							
Patient Identifier	Date of birth	Sex	Weight					
381	3-26-96	female	31	lbs				
B. Adverse event	or product p	roblem						
Adverse Event & Product Problem								
Outcomes attribut	Outcomes attributed to adverse event							
death	disability							
☐ life-threatening	☐ life-threatening ☐ congenital anomaly							
$\square_{ m hospitalization}$	required in	ntervention						
other: rash alon	g the neck							
Date of event 9-5-	-00 Date	e of report	9/13/2	2000				
Describe event or	problem							
daughters-head was	-							
lice, did not know w				ened				
nix used it next day	, live louse and	rasn appear	ea.					
Relevant tests/laboratory data								
Other relevant his	story, including	g preexisti	ng condi	tion				

C. Suspect medication(s)						
Name: Nix						
Dose, frequency, route use Therapy dates						
pottle of nix-used once 9-5-			00			
			to 9-13-00			
Diagnosis for us	p	Ī	Event :	abated after use		
nixs, olive oil, rid			stopped or dose reduced			
iixs, olive oli, ild	spray					
			doesn	t apply		
Lot#	Exp. date			reappeared after		
		r	eintro	duction		
NDC# -		_	yes			
	3'1 2					
Concomitant me				إ		
we have been usin	-	-	-			
she had lice and i						
and my family wh			s comb	oing constantly		
D. Suspect med	lical device)				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
			$\square_{\rm h}$	ealth professional		
				user facility		
distributor				istributor		
	Expiration date			ration date		
nodel #						
catalog #		If implanted, give dat				
serial #						
ot #			If exp	planted, give date		
other #						
Device available						
	returned		nufact	urer//		
Concomitant me	dical produ	cts				
E. Reporter						
Name and address phone # (781)449-6487						
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
$\mathbf{\nabla}_{\mathrm{yes}}$	_	Jaulul	1	Also reported to manufacturer		
f you do NOT want your identity						
•	•	•	, 🔳	distributor		
lisclosed to the ma	muracturer, p	тасе а	ш Ш	- 01501100001		

A. Budinad Life								
A. Patient Info								
Patient Identif		Date of k	oirth	Sex	Weight			
378	-	07-20-62		female	150	lbs		
B. Adverse ev	ent	or prod	uct pi	roblem				
		Adver	se Eve	ent				
Outcomes attri	Outcomes attributed to adverse event							
death	death disability							
□life-threaten	☐ life-threatening ☐ congenital anomaly							
hospitalizat	ion	\square_{requ}	ired in	ntervention				
other: keep	goiı	ng to the	doctors	S				
Date of event	8-2-	2000	Date	of report	9/10/2	2000		
Describe event	or	problem		-				
Had scabbies. V		_	ith Lv	ndane and	5 weeks la	ater		
I am still iching			-					
mind. I have be		•				•		
reaction to the c	rear	n that I aj	oplied.					
Relevant tests/laboratory data								
Other relevant	his	tory, inc	ludina	preexisti	ng condi	ion		
I am till iching.					ng conun			
ann ann ionnig.	501	ne one pre	ase ne	ip iiie.				

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name: Kwell				
Lyndane				
·			rapy d	ates
Only once			2000	
				to 8-6-2000
Diagnosis for us	0		Event	abated after use
_	C			d or dose reduced
Lyndane				u 01 u050 10uu00u
	<u> </u>		no	
Lot #	Exp. date			reappeared after
			reintro	oduction
NDC# -		\dashv	yes	
	3212	-4:		
Concomitant me	aicai produ	cts		
D 0				
D. Suspect med	dical device)		
Brand name				
Type of device			10	
Manufacturer na	ame and add	iress	_	ator of device
			l III	ealth professional
				ser facility
				istributor
			Expi	ration date
model #			T.C :	-lautad atus data
catalog #			- II IM]	planted, give date
serial # lot #			T.C.	1 (1 . 1 .
lot # other #			III exp	planted, give date
Device available	fo o	9		
yes \square_{no}			anufact	urer / /
Concomitant me				<u></u>
	P			
E. Reporter				
Name and addre				(781)449-6487
The National Pe	diculosis A	ssoc	ciation	
P.O. Box 610189, Newton, MA. 02461				
Health professio	nal Occuj	patio	n	Also reported to
)			manufacturer
If you do NOT wa	nt your identi	ity		user facility
disclosed to the ma			an 🔲	□distributor

	_			
A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
373	7-17-75	female	120	lbs
B. Adverse event	or product p	roblem		
	Adverse Ev	ent		
Outcomes attribut	ted to adverse	event		
death	disability			
☐ life-threatening	Congenital	anomaly		
□ hospitalization	required in	ntervention		
other: major sk	in irritation			
Date of event 9-0:	5-00 Dat	e of report	9/7/2	2000
Describe event or	problem			
used the product Ri		a major ras	h on my h	nead,
neck, ears, chest and	d shoulders had	to miss wo	rk due to	
itching.				
Dalamant tagta/laba	4			
Relevant tests/labo	oratory data			
				.•
Other relevant his	story, includin	g preexisti	ng condi	tion
none				

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: Rid					
Dose, frequency,	route use	The	rapy d	ates	
1		9-0:			
				to 9-05	
Diagnosis for us	ρ.		Event	abated after use	
head lice	•		stopped or dose reduced		
nead nice					
			no		
Lot#	Exp. date			reappeared after	
			reintroduction		
NDC# -			doesn'	t apply	
	-	_			
Concomitant me	dical produ	cts			
none					
D 0					
D. Suspect med	lical device)			
Brand name					
Type of device			10		
Manufacturer na	ime and add	iress		ator of device	
				ealth professional	
			user facility distributor		
			Expi	ration date	
model #			- TE :	ulautad atus data	
catalog #			- II IM]	planted, give date	
serial # lot #				1 4 1 1 1 4	
other #			- III exp	planted, give date	
Device available	f	9	1		
yes \square_{no}				uror / /	
Concomitant me	dical produ	cts	ianuraci		
	F				
E. Reporter					
Name and addre	SS	p	hone #	(781)449-6487	
The National Pe	diculosis A	sso	ciation		
P.O. Box 610189	, Newton, M	IA.	02461		
Health professio	nal Occup	oatio	n	Also reported to	
\bigvee_{yes} \square_{no}	_			manufacturer	
f you do NOT want your identity user facility					
disclosed to the manufacturer, place an distributor					

A Dark					
A. Patient Informa					
Patient Identifier	Date of b	irth	Sex	Weigl	ıt
363	10/24/94		male	48	lbs
B. Adverse event	or produ	ıct pı	oblem		
	Product	Prob	lem		
Outcomes attribute	ed to adv	erse e	vent		
\Box death	□disab	ility			
☐ life-threatening	\Box_{cong}	enital	anomal	y	
hospitalization	\square_{requi}	red in	iterventi	on	
other:					
Date of event 8/8/0	00	Date	of repo	ort 9	/3/2000
Describe event or p		Dan	orrep	<i></i>	3/2000
Sibling infestation. manual removal imp Rid,Nix,A200 - mini Lindane - effective o	oractical.U imal kill. on live, <10	sed: Adult 00% c	s alive.	on (4 cmid	ren)
Other relevant his Had this happen dur same course of treat nurses recommendat the exception of the	ing fall of ment with tion) of a 1	1999 the i mayor	also. V ncluded naise tre	Vent throust attempts atment. V	gh (at Vith

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: lindane					
Dose, frequency, route use The			rapy d	ates	
As per directions		7/29	000	to	
				8/11/00	
Diagnosis for us	e		Event	abated after use	
Control of lice			stoppe	d or dose reduced	
			no		
Lot #	Exp. date		Event	reappeared after	
	_			duction	
NDC# -	-		doesn'	t apply	
Concomitant me	dical produ	cts			
	•				
D. Suspect med	lical device				
Brand name	arour dovioc				
Type of device					
Manufacturer na	me and add	Irocc	Oper	ator of device	
Manufacturer na	iiic anu auc	11 655	ı Â		
				ealth professional	
			user facility distributor		
			_		
			Expii	ration date	
model #			If im	planted, give date	
catalog #				pianicu, give uate	
serial #			T.C.	1 4 1 1 1 4	
lot # other #			- III exp	planted, give date	
	e 1 4				
Device available $\square_{ m yes} \ \square_{ m no}$			anufact	urer / /	
Concomitant me	dical produ	cts	arrarae	.droi/_/	
Concomitant medical products					
E. Reporter					
Name and addre	SS	p	hone #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occuj	patio	n	Also reported to	
$\mathbf{v}_{\mathrm{yes}} \square_{\mathrm{no}}$)			manufacturer	
If you do NOT want your identity user facili			user facility		
disclosed to the ma			an 🔲	distributor	

		-			
	nt Inform				
Patient 1	Identifier	Date of birth	Sex	Weight	
	358	6/26/91	female	75 ll	bs
B. Adve	rse event	or product	problem		
	Advers	e Event & Pr	oduct Probl	em	
Outcom	es attribut	ted to advers	e event		
deatl	h	disabilit	y		
$\Box_{\text{life-t}}$	hreatening	□ congenit	al anomaly		
\square_{hosp}	italization	required	intervention	ı	
other	r: headache	es			
Date of	event 10/9	99/ D a	te of report	9/2/200)()
Describe	e event or				
		t headlice 1yr.	ago,I used ri	d,nix,&	
_		ing would kill		_	
		ed getting hea		used the	
products	about 10X	with no luck	,		
Relevan	t tests/labo	oratory data			
Other re	elevant his	story, includi	ng preexist	ing conditio	 n
o ther re		, tory, meruur	ng preemse	ing conditio	

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Nix					
Rid, gen	eric brand				
Dose, frequency	, route use	The	rapy d	ates	
about once a mon		8/99			
			to 8/00		
Diagnosis for us	e		Event :	abated after use	
lice were never co		ed.		d or dose reduced	
	1 5		doesn'	t apply	
Lot#	Exp. date			reappeared after	
				reappeared after oduction	
NDC# -	-		doesn'	t apply	
Concomitant me	dical produ	cts	1		
none					
D. Suspect med	dical device)			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
				ealth professional	
				ser facility	
				istributor	
				ration date	
model #			Lipi	auton dute	
catalog #			If im	planted, give date	
serial #			-	. , ,	
lot #			If ext	planted, give date	
other #				, , ,	
Device available	for evaluati	ion?			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$				urer/_/	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	SS	р	hone #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189	, Newton, M	ΙΑ. (02461		
Health professio	nal Occup	oatio	n	Also reported to	
$\mathbf{\nabla}_{\mathrm{yes}} \square_{\mathrm{no}}$	_			manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma			an 🔲	distributor	

A. Patient Inform	ation					
Patient Identifier	Date of birth	Sex	Weight			
356	11-02-93	female	119	lbs		
B. Adverse event	or product p	roblem				
	Adverse Ev	ent				
Outcomes attribut	ted to adverse	event				
death	disability					
☐ life-threatening	□ congenital	anomaly				
hospitalization	required in	ntervention				
other: difficulty	breathing -seve	ere headach	e after tre	atm		
Date of event 2-1:	5-00 Date	e of report	9/1/2	2000		
Describe event or	problem					
daughter had severe						
lice treatment, could	dnt catch breath	during use	of treatm	ent.		
Relevant tests/laboratory data						
Other relevant his	story includin	a nyoovisti	na aandi	tion		
Other relevant his	story, including	g preexisti	ng contr	uon		

Triage Unit Sequence #	

-				-	
C. Suspect med	lication(s)				
Name: Nix					
Daga fra		TP1.		~4~~	
Oose, frequency,	route use		erapy d	ates	
lirections on box		2/18	3/00	to	
				2/19/00	
Diagnosis for us	e		Event	abated after use	
nave no idea what	you mean he	ere	stoppe	d or dose reduced	
			yes		
Lot#	Exp. date		,		
201 11	Lap. dute			reappeared after	
			reintro	duction	
NDC# -	_		yes		
		-4			
Concomitant me	dical produ	cts			
D. Suspect med	lical device)			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			1 —	ealth professional	
				ser facility	
				istributor	
			Expii	ration date	
nodel #			If im	planted, give date	
catalog #			- ******	piuricu, give uate	
erial # ot #			Tf aver	alanted give data	
ot # other #			- In ext	planted, give date	
	£11	0			
Device available yes no					
Concomitant me			ianuract	.u1Cl//	
oncomitant me	uicai pi ouu	cis			
E. Reporter					
Name and addre	ss	р	hone #	(781)449-6487	
The National Pe	diculosis A	Ê		` '	
Γhe National Pediculosis Association P.O. Box 610189, Newton, MA. 02461					
Health profession		patio	n	Also reported to	
$\mathbf{v}_{\mathrm{yes}} = \mathbf{u}_{\mathrm{nc}}$)			manufacturer	
f you do NOT war	-	-]	user facility	
lisclosed to the ma	nufacturer, p	lace	an 🔳	□distributor	

A. Patient	Inform	ation				
Patient Ide	entifier	Date of b	irth	Sex	Weight	
	354	4/6/90		male	85	lbs
B. Advers	e event	or produ	uct pi	oblem		
	Advers	e Event &	Prod	uct Proble	m	
Outcomes	attribut	ed to adv	erse e	event		
death		□disal	oility			
□ life-thre	eatening	\Box_{cong}	enital	anomaly		
\Box_{hospita}	lization	\square_{requ}	ired in	tervention		
other: s	severe ra	sh & sores	S			
Date of eve	ent 11/9	95/	Date	of report	8/31/2	2000
Describe e	vent or	problem				
fall 95- larg					npox sore	
&product fa	ailure s	summer 00)-prod	uct failure		
Relevant tests/laboratory data						
Other rele	vant his	story, incl	uding	g preexisti	ng condi	tion
none						

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: Nix					
rid					
Dose, frequency,	, route use	The	rapy d	ates	
used according to	labeled	11/9	5		
instructions				to 12/95	
Diagnosis for us	e	<u> </u>	Event	abated after use	
head lice				d or dose reduced	
nead fice					
			yes		
Lot#	Exp. date]	Event 1	reappeared after	
]	reintro	duction	
AUD CI II			yes		
NDC# -	-		-		
Concomitant me	dical produ	cts			
D. Suspect med	dical device)			
Brand name					
Type of device			Т.		
Manufacturer na	ime and add	iress	_		
			l Hh	ealth professional	
				ser facility	
				istributor	
			Expi	ration date	
model #			TC:	ulautad atus data	
catalog #			lii im	planted, give date	
serial # lot #			TE	alament at a total	
lot # other #			ıı exp	planted, give date	
	C]		
Device available $\square_{ m yes} \ \square_{ m no}$			anufact	uror / /	
Concomitant me			anuraci	.u1Cl/_/	
Concomitant me	arcar produ	Cus			
E. Reporter					
Name and addre	ss	pł	none #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occup	patio	n	Also reported to	
$\mathbf{v}_{\mathrm{yes}}$,			manufacturer	
If you do NOT was	nt your identi	ity		user facility	
disclosed to the ma			an 🔲	□distributor	

A. Patient Inform	ation					
Patient Identifier	Date of birth	Sex	Weight			
353	10/16/95	female	62 lbs			
B. Adverse event	or product p	roblem				
	Product Prol	olem				
Outcomes attribut	ted to adverse	event				
death	disability					
☐ life-threatening	□ congenital	anomaly				
$\square_{ m hospitalization}$	□required i	ntervention				
other:						
Date of event 08/2	20/00 Dat	e of report	8/30/2000			
Describe event or						
have tried 2 separate	=	has failed	to kill the lice			
Relevant tests/labo	oratory data					
	·					
Other relevant his	story, includin	g preexisti	ng condition			
	• /	61	8			

Triage Unit Sequence #	

<u> </u>				
C. Suspect me	dication(s)			
Name: Nix				
lindane				
Dose, frequency	, route use	Ther	apy d	ates
once for the linda	ne, 2x with	8/05/	00	
nix				to 08/30/00
Diagnosis for us	se	F	Event	abated after use
head lice				d or dose reduced
nead nee			doesn	t apply
Lot#	Exp. date	—⊨		
Lot #	Exp. uate			reappeared after
		r	eintro	oduction
NDC# -		- ⋅	doesn	t apply
Concomitant me	dical produ	cts		
	dicui produ	CUS		
D. Suspect me	dical device			
Brand name				
Type of device				
Manufacturer n	ame and add	iress	Oper	ator of device
			\square_{h}	ealth professional
			l □u	ser facility
			\square_{d}	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot # other #			If exp	olanted, give date
	•			
Device available $\square_{ m yes} \ \square_{ m no}$	returned		nufoot	uror / /
Concomitant me			nuraci	urer//
Concommunit in	dicui produ	CUS		
E. Reporter				
Name and addre				(781)449-6487
The National Pe	ediculosis A	ssoci	ation	
P.O. Box 610189	9, Newton, N	1A. 02	2461	
Health professio		pation	1	Also reported to
$\mathbf{V}_{\mathrm{yes}} \square_{\mathrm{ne}}$	0			manufacturer
If you do NOT wa	•	•		user facility
disclosed to the m	anufacturer, p	lace a	n 🔳	□distributor

A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
337	02/01/19	95	female	55	lbs
B. Adverse event	or produ	ıct pı	oblem		
	Product	Prob	lem		
Outcomes attribut	_		event		
death	∐disab	-			
☐ life-threatening			anomaly		
hospitalization	□requi	red in	tervention		
other:					
Date of event 07/2	22/2000	Date	of report	8/23/2	2000
Describe event or					
We have treated wit					onth
of treatments we sti	II can not g	get rid	of the lice	•	
Dalamant tasta/lab	4	.4			
Relevant tests/labo	oratory da	ıta			
Other relevant his	story, incl	uding	z preexisti	ng condi	tion
	3 ,		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: Nix				
Rid and I	Lindane pres	cripti	ion	
Oose, frequency,	route use	The	rapy d	ates
2 x a week rid or n	ix 1 x	07/2	2/00	to
indane				08/22/00
Diagnosis for us	e]	Event	abated after use
•		5	stoppe	d or dose reduced
			doesn'	t apply
Lot #	Exp. date]	Event 1	reappeared after
]1	reintro	oduction
IDC #			doesn'	t apply
NDC # -	-			- - -
Concomitant me	-			
	-		-	her treatments we
neard will smother nair?	r or neip reai	uce tr	ne nits	from sticking to
D. Suspect med	lical davies			
	lical device	;		
Brand name				
Type of device Manufacturer na	me and add	lrece	Oper	ator of device
vianuiactuiti Ha	iiic anu auc	11 699	1 —	
				ealth professional
user facility distributor				
1.1.4			Expii	ration date
nodel			If im	planted, give date
erial #				, g
ot #			If ext	olanted, give date
other #				
Device available	for evaluati	ion?	1	
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to ma	anufact	urer/_ /
Concomitant me				
E. Reporter				
Name and addres	ss	pł	one#	(781)449-6487
Γhe National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, M	1 A. 0	2461	
Health profession	nal Occup	patio	n	Also reported to manufacturer
	* * * * * * * * * * * * * * * * * * *			user facility
f you do NOT war lisclosed to the ma		-	n 🔳	distributor
isciosca to the Illa	αααα	ruce a		

A. Patient	Inform	ation		
Patient Id	entifier	Date of birth	Sex	Weight
	336	01-18-93	female	60 lbs
B. Advers	e event	or product p	roblem	
		Product Prob	lem	
Outcomes	attribut	ted to adverse o	event	
death		disability		
$\Box_{\text{life-thr}}$	eatening	□ congenital	anomaly	
\square_{hospita}	lization	□required in	ntervention	
other:		•		
Date of ev	ant 6/26	5/8/21 D ate	e of report	8/23/2000
Describe e			or report	6/23/2000
		problem rring and i have		
		idy.i am scared		
to retreat a		•		
i dont				
-		d of doing somel		
_		the boxes say n	ot to exced	e
recommene	ed doses.			
Relevant t	ests/labo	oratory data		
reie valle t	CD CD/ ICID	ratory auta		
	vant his	story, including	g preexisti	ng condition
none				

Triage Unit Sequence #	

dication(s)		
lane,and rid		
, route use	Therapy d	lates
doses on	6/25/00	t o
		to 8/22/00
e	Event	abated after use
	stoppe	ed or dose reduced
	doesn	't apply
Exp. date	Event	reappeared after
		oduction
	doesn	't apply
-	doesn	с пррту
dical produ	cts	
والمسالة والمسائد		
dicai device)	
ame and add	lress One	rator of device
ame and ade		nealth professional
		ser facility
		listributor
	Expi	ration date
	If im	planted, give date
	Tf or	
	II ex	planted, give date
C11		planted, give date
for evaluati	ion?	
returned	ion? to manufac	
	ion? to manufac	
returned	ion? to manufac	
returned dical produc	ion? to manufac	turer _ /_ /
returned dical productions	ion? to manufac cts phone #	turer _ / /
returned dical productions A	ion? to manufacts phone #	turer _ / /
returned dical productions of the second sec	phone #	turer _ / /
returned dical productions of the control of the co	phone #	turer/_ /
returned dical productions of the second sec	phone # ssociation IA. 02461	turer _ / /
	dane, and rid , route use doses on Exp. date - dical production	dane, and rid , route use doses on 6/25/00 Event stoppe doesn Exp. date Event reintre doesn dical products Compared to the compared to th

Patient Identifier Date of birth Sex Weight					
334 05/07/1996 female 41	lbs				
B. Adverse event or product problem					
Product Problem					
Outcomes attributed to adverse event					
☐ death ☐ disability					
life-threatening congenital anomaly					
☐ hospitalization ☐ required intervention					
other: Ineffective					
Date of event 08/20/00 Date of report 8/22/20	000				
Describe event or problem					
Nothing is working.					
Relevant tests/laboratory data					
Other relevant history, including preexisting condition	on				
None					

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: lindane				
Nix				
Dose, frequency,	route use	The	rapy d	ates
Lindane 2 weeks l	ater Nix	08/0	1/2000	
				to 08/18/2000
Diagnosis for us	•		Event	abated after use
Diagnosis for us	e			d or dose reduced
Ineffective				
			doesn'	t apply
Lot#	Exp. date		Event 1	reappeared after
			reintro	duction
			doesn'	t apply
NDC# -	-		200011	rr-J
Concomitant me	dical produ	cts		
Herbal shampoo.				
D. Suspect med	lical device)		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
			\square_{h}	ealth professional
			□ u:	ser facility
			$\Box_{\mathbf{d}}$	istributor
			Expir	ation date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	olanted, give date
other #				
Device available yes no				
Concomitant me				urer/_/
Concomitant me	uicai produ	LIS		
E. Reporter				
Name and addre		드		(781)449-6487
The National Pe				
P.O. Box 610189	, Newton, M	ΙΑ. (02461	
Health professio	nal Occuj	oatio	n	Also reported to
$ \mathbf{V}_{\text{yes}} \square_{\text{no}} $)			manufacturer
If you do NOT wa	nt your identi	ty	_	user facility
disclosed to the ma	ınufacturer, p	lace	an 🔲	□distributor

A. Patient Inform	ation				
Patient Identifier	Date of birth	Sex	Weight		
333	9/29/90	female	105	lbs	
B. Adverse event	or product p	roblem			
	Product Prol	olem			
Outcomes attribut	ted to adverse	event			
death	disability				
☐ life-threatening	Congenital	anomaly			
hospitalization	☐ required i	ntervention			
other:					
Date of event 19/9	99/ Dat	e of report	8/22/2	2000	
Describe event or	problem				
Repeated treatment	failure (Nix, Ri	d, Lindane,	etc) for		
head lice					
Relevant tests/laboratory data					
Other relevant his	story includin	g nreevisti	ng candi	tion	
Other relevant his	, tory, meruum	g preexisti	ng conur	uon	

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: Rid					
Dose, frequency,	route use	Ther	apy d	ates	
Every two weeks	or so for	1999			
the last year				to 9/2000	
Diagnosis for us	e	F	Event	abated after use	
Headlice				d or dose reduced	
rieadrice					
.	D 1.		no		
Lot #	Exp. date			reappeared after	
		r	eintro	oduction	
NDC# -		-	yes		
	- 				
Concomitant me	aicai produ	cts			
B. 0	liant dania				
D. Suspect med	ilcai device)			
Brand name					
<u>Fype of device</u> Manufacturer na	mo and add	lmagg	Onor	ator of device	
vianuiaciurei na	illie allu auc	11 688	I —		
				ealth professional ser facility	
				istributor	
			<u> </u>		
3.1//			Expii	ration date	
model			If im	planted, give date	
serial #			ĺ ,	r, g	
lot #			If ext	planted, give date	
other #				, , , , , , , , , , , , , , , , , , , ,	
Device available	for evaluati	ion?	1		
yes no returned to manufacturer _/_/					
Concomitant medical products					
E. Reporter					
Name and addre	aa	J.	one #	(781)449-6487	
				(/81)449-048/	
The National Pediculosis Association					
P.O. Box 610189	, Newton, N	1A. 0	2461		
Health professio	_	pation	1	Also reported to	
$ \mathbf{V}_{\text{yes}} \square_{\text{no}} $				manufacturer	
If you do NOT was	-			user facility	
disclosed to the ma	nufacturer, p	lace a	n 🔲	□distributor	

A. Patient	Inform	ation				
Patient Ide	entifier	Date of b	irth	Sex	Weight	
	328	09/23/00)	female	21	lbs
B. Advers	e event	t or prod	uct p	roblem		
		Product	Prob	lem		
Outcomes	attribut	ted to adv	erse e	event		
death		\Box_{disa}	bility			
□ life-thre	eatening	\Box_{cong}	genital	anomaly		
\Box_{hospita}	lization	\square_{requ}	ired ir	ntervention		
other:						
Date of eve	ent 7/26	5/00	Date	of report	8/21/2	2000
Describe e	vent or	problem				
Rid comple						
failed. Pedi worked. I v						
have lived v			me sic	ie effects fi	ist. I wo	uia
nave nvea v	with the	ougs				
Relevant te	ests/labo	oratory d	ata			
Other rele	vant his	story, inc	luding	g preexisti	ng condi	tion

Triage Unit Sequence #	

C. Suspect me	edication(s)			
Name: lindane				
rid and	nix			
Dose, frequency, route use The		Ther	erapy dates	
lindane used onl	y once	7/26/	00	4
rid used once and	l nix once			to 8/1/00
Diagnosis for u	se	F	Event	abated after use
head lice		S	toppe	d or dose reduced
		1	no	
Lot #	Exp. date	E	Event	reappeared after
				duction
			VAC	
NDC# -	-		yes	
Concomitant m	edical produ	cts		
rid 7/26/00 nix 7	7/28/00 lindan	e 8/1/	00	
D. Suspect me	edical device	•		
Brand name				
Type of device				
Manufacturer i	name and add	lress	Oper	ator of device
			\square_{h}	ealth professional
				ser facility
				istributor
				ration date
model #			Z.Api.	auton dute
catalog #			If im	planted, give date
serial #				
lot #			If ext	olanted, give date
other #			•	, , ,
Device availabl	e for evaluat	ion?		
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			nufact	urer/_/
Concomitant m	edical produ	cts		
E. Reporter				
Name and addr	ess	ph	one#	(781)449-6487
The National F	ediculosis A	ssoci	ation	
P.O. Box 610189, Newton, MA. 02461				
Health professi	onal Occuj	pation	1	Also reported to
	10			manufacturer
If you do NOT w	ant your ident	ity		user facility
disclosed to the n	-	-	n 🔲	distributor

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
325	9-28-1997	female	34	lbs
B. Adverse event	or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ted to adverse o	event		
\Box_{death}	disability			
☐ life-threatening	Congenital	anomaly		
hospitalization				
other:	•			
Date of event 8-10	0-00 Date	e of report	8/19/20	000
Describe event or		отторого	0,13,20	
i applied kwell shar	=	ted by both	the doctor	
and pharmacist and	-	-	200001	
	-			
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng conditi	on
none				

Triage Unit Sequence #	

C. Suspect medication(s)				
Name: Kwell				
Dose, frequency	, route use	The	rapy d	ates
pharmacist said t	o use about	8-10)-00	
an ounce				to 8-17-00
Diagnosis for u	se			abated after use
doctor diagnosed	head lice		stoppe	d or dose reduced
			doesn'	t apply
Lot#	Exp. date		Event	reappeared after
			reintro	duction
NDC# -			doesn'	t apply
	-			
Concomitant m	=			
when 1st applica		_		
week and then re	applied.still d	lid n	ot work	· ·
D. Suspect me	dical device	•		
Brand name				
Type of device				
Manufacturer n	ame and add	dress	Oper	ator of device
			\square_{h}	ealth professional
				ser facility
			\square_{d}	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	olanted, give date
other #				<u>-</u>
Device available □ _{yes} □ _{no}			· ·	, ,
Concomitant m				urer//
Concomitant in	edicai produ	Cis		
E. Reporter				
Name and address phone # (781)449-6487				
The National Pediculosis Association				
P.O. Box 610189, Newton, MA. 02461				
Health profession	onal Occuj	patio	n	Also reported to manufacturer
				user facility
If you do NOT ware disclosed to the manager of the			an 🔳	distributor
disclosed to the fr	iamuracturer, p	nace	ali 🔳	GIBUIDUOI

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
324	1-12-95	female	54	lbs
B. Adverse event	t or product p	roblem		
Advers	e Event & Prod	luct Proble	em	
Outcomes attribut	ted to adverse o	event		
death	disability			
☐ life-threatening	□ congenital	anomaly		
$\square_{ m hospitalization}$	required in	ntervention		
other: O.D. on	chemicals			
Date of event 7/11	1/00 Date	e of report	8/19/2	2000
Describe event or	problem			
My daughter was gi				
was told by the doc for 10-15 min.	tor to put 16oz.	on her hea	d leave it	on
101 10-13 mm.				
Relevant tests/labo	oratory data			
Other relevant his	story including	n proovieti	na condi	tion
Other relevant his	story, menum	g pi eexisti	ng conun	поп

Triage Unit Sequence #	

C. Suspect med	dication(s)		
Name: lindane			
actene,cl	ear,nix,rid,eq	luate	
Dose, frequency	, route use	Therapy o	lates
16oz.of LIndane,n	ix rid	7/11/00	4
Clear,equate			to 8/12/00
Diagnosis for us	e	Event	abated after use
resistent head lice		stoppe	ed or dose reduced
		doesn	ı't apply
Lot#	Exp. date	Event	reappeared after
			oduction
		doesr	ı't apply
NDC# -	-	doesi	генриу
Concomitant me	dical produ	cts	
sulfer antibiotic fo	or infection of	n scalp.	
D. Suspect med	dical device	9	
Brand name			
Type of device		l	
Manufacturer na	ame and add	ا آ	rator of device
			nealth professional
			ıser facility listributor
"		Expi	ration date
model # catalog #		If im	planted, give date
serial #			1
lot #		If ex	planted, give date
other #			, ,
Device available			
	Ireturned		turer/_/
Concomitant me	uicai produ	cis	
E. Reporter			
Name and addre	SS	phone #	(781)449-6487
The National Pe	diculosis A		
P.O. Box 610189	, Newton, M	1 A. 02461	
Health professio	nal Occuj	IA. 02461 pation	Also reported to
	nal Occup	oation	Also reported to manufacturer user facility

2120671		_		
A. Patient Inform	ation			
Patient Identifier	Date of bir	th Sex	Weig	ht
318	11/4/93	female	50	lbs
B. Adverse event	or produc	t problen	ı	
Advers	e Event & P	roduct Pr	oblem	
Outcomes attribut	ted to adver	se event		
death	□disabil	ity		
☐ life-threatening	\Box_{congen}	ital anoma	ly	
hospitalization	\square_{require}	d intervent	ion	
other: none				
Date of event 8/11	1/00	Date of rep	ort 8/1	16/2000
Describe event or				
Found live lice and	=	with NIX	and cleane	ed all
bedding, bagged all				
days later still findir	ng live lice d	aily and m	any nits. V	We
check 2xs daily for	them.			
Relevant tests/labo	ratory data	,		
Refevant tests/labe	ratory date	•		
Other relevant his				
day 4 developed 102			nd exhaust	teddid
the nix cause it or d	id she get the	e flu?		

Triage Unit Sequence #	

				'
C. Suspect me	dication(s)			
Name: Nix				
permeth	rin 1%			
Dose, frequency	, route use	The	rapy d	ates
1/3 of 2oz bottle,	once	8/11	[4-
				to 8/11
Diagnosis for us	se		Event	abated after use
nits and lice			stoppe	d or dose reduced
			no	
Lot #	Exp. date		Event	reappeared after
	1			duction
NDC# -	-		uoesn	t apply
Concomitant me	edical produ	cts		
picked her head d	aily 2 xs a da	y fo	r bugs a	and nits.
D. Suspect me	dical device	9		
Brand name				
Type of device Manufacturer n	ome and add	lnoss	Onor	otor of dovice
Manufacturer ii	ame and add	11 688	آ ا	ator of device
				ealth professional ser facility
				istributor
				ration date
model #			Expi	auon uate
catalog #			If im	planted, give date
serial #			-	
lot #			_ If exp	olanted, give date
other #				
Device available				
	returned		anufact	urer//
Concomitant me	cuicai produ	CIS		
E. Reporter				
Name and addre	ess	p	hone #	(781)449-6487
The National Pe	ediculosis A	ssoc	ciation	
P.O. Box 610189	, Newton, M	1A. (02461	
Health profession		oatio)n	Also reported to
✓ yes □ne				manufacturer
If you do NOT wa	•	•		user facility distributor
disclosed to the m	anutacturer, p	lace	an 🔳	

	-			
A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
314	03-08-93	female	55 11	bs
B. Adverse event	or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ted to adverse o	event		_
death	disability			
☐ life-threatening	_	an amalı.		
I — ~		•		
hospitalization	□ required in	tervention		_
other:				
Date of event 6/00) Date	of report	8/13/200	00
Describe event or	problem			
She has had head lie	ce for about 2 m	onths, I hav	ve tried ever	y
product including li		nd pick for	hours daily	
but still cannot get	rid of it.			
Relevant tests/labo	oratory data			
Other relevant his	towy including	iati	na sonditio	
Other relevant his	story, including	g preexisu	ng conaitio	n

Triage Unit Sequence #	

•				
C. Suspect me	dication(s)			
Name:				
Numero	ous			
Dose, frequency	, route use	The	rapy d	ates
as directed	,	6/00		
as directed		0,00		to 8/00
Diagnosis for us	20		Event	abated after use
lice	sc			d or dose reduced
nce				
- . "	ln 1		no	
Lot#	Exp. date			reappeared after
			reintro	duction
NDC# -	_		yes	
Concomitant me	adical produ	ete		
Concomitant III	cuicai produ	cis		
D. Suspect me	dical device			
Brand name	aloal dovio			
Type of device				
Manufacturer n	ame and add	lress	Oper	ator of device
			1 —	ealth professional
			\square_{u}	ser facility
			\square_{d}	istributor
			Expi	ration date
model #			_	
catalog #			If im	planted, give date
serial #				
lot # other #			- If exp	planted, give date
Device available $\square_{ m yes} \ \square_{ m no}$	returned		anufaat	uror / /
Concomitant me			anuraci	urer//
	ourour produ	•••		
E. Reporter				
Name and addro		드		(781)449-6487
The National Po	ediculosis A	ssoc	ciation	
P.O. Box 610189	9, Newton, N	1A. (02461	
Health profession		patio	n	Also reported to
$\mathbf{V}_{\mathrm{yes}} \mathbf{\square}_{\mathrm{n}}$	0			manufacturer
If you do NOT wa	•	-		user facility
disclosed to the m	anufacturer, p	lace	an 🔳	□distributor

A. Patient Inform	nation				
Patient Identifie	Date of b	oirth	Sex	Weight	
312	00-00-19	957	female	150	lbs
B. Adverse ever	t or prod	uct pi	roblem		
	Adver	se Eve	ent		
Outcomes attribu	ited to adv	erse e	event		
death	_	bility			
☐ life-threatening	g ∐cong	genital	anomaly		
hospitalization	n □requ	ired in	ntervention		
other: couldn'	work				
Date of event 08	-11-00	Date	of report	8/11/2	2000
Describe event or					
used lindane and s	prayed with	h RID	and feel di	soriented	and
eyes affected					
D 1 44 4 7 1					
Relevant tests/lab	oratory d	ata			
Other relevant h	istory, inc	ludina	o preexisti	ng candi	tion
	5, 1110		5 Preemser	ng conur	

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: lindane				
RID spra	ıy			
Dose, frequency,	route use	The	rapy d	ates
twice		07-0	00-00	
				to 08-11-00
Diagnosis for us	ρ		Event	abated after use
scabies	•			d or dose reduced
scables				
			no	
Lot #	Exp. date		Event	reappeared after
			reintro	duction
NIDC #			doesn'	t apply
NDC# -	<u> </u>			
Concomitant me	=			
feeling much wors	se after spray	ing	the RID	•
D. Suspect med	lical device	,		
Brand name				
Type of device			1.	
Manufacturer na	ime and add	lress		ator of device
				ealth professional
				ser facility
				istributor
			Expi	ration date
model #			TC:	
catalog #			- II IM]	planted, give date
serial # lot #				
other #			- If exp	planted, give date
	C			
Device available $\square_{\mathrm{yes}} \square_{\mathrm{no}}$				uror / /
Concomitant me	dical produ	rts	ianuract	.u1Cl/_/
Concomment me	arear produ	13		
E. Reporter				
Name and addre	ss	p	hone #	(781)449-6487
The National Pe	diculosis A	sso	ciation	
P.O. Box 610189	, Newton, M	ΙΑ. (02461	
Health profession				Also reported to
$\mathbf{V}_{\mathrm{yes}}$ \square_{nc}	_			manufacturer
If you do NOT wa	nt your identi	ty		user facility
disclosed to the ma			an 🔲	distributor

2120011					
A. Patient Inform	ation				
Patient Identifier	Date of bi	irth	Sex	Weight	
311	20-05-90		female	67	lbs
B. Adverse event	or produ	ıct pr	oblem		
Advers	e Event &	Prod	uct Probl	em	
Outcomes attribut	ted to adve	erse e	vent		
death	\Box_{disab}	ility			
□ life-threatening	\Box_{cong}	enital	anomaly		
hospitalization	□requi	red in	tervention	1	
other:					
Date of event 8-08	8 00	Doto	of repor	£ Q/11/	2000
Describe event or		Date	or repor	0/11/	2000
Had grand mal seizi pharmacist. aunt sh been treated 3 week at this time	ampooed I	her w	ithout kno	wing she	had
Other relevant his she was perfectly no head lice was 7 year	story, inclu	uding ore thi	s. first en	counter w	

C. Suspect med	lication(s)				
Name: Nix					
RID spra	ay				
Dose, frequency,	route use	The	rapy d	ates	
1		08-0	08-00		
				to 08-11-00	
Diagnosis for us	e		Event	abated after use	
head lice	•			d or dose reduced	
nead nce					
			no		
Lot #	Exp. date		Event	reappeared after	
			reintro	duction	
NIDC #			doesn'	t apply	
NDC# -	-				
Concomitant me	=				
Now diagnosed as	epileptic and	d ha	d dilanti	in IV in ER and	
put on Depacote					
D. Suspect med	lical device)			
Brand name					
Type of device	1 1			4 63 .	
Manufacturer na	ime and add	ires		ator of device	
	health professional				
user facility distributor					
			Expi	ration date	
model #			- If im	planted, give date	
catalog #			- 11 1111	pianieu, give uate	
serial # lot #			If over	olanted, give date	
other #			- III CAL	nameu, give date	
Device available	for avaluati	ion?			
$\square_{\text{yes}} \square_{\text{no}}$				curer / /	
Concomitant me					
	_				
E. Reporter					
Name and addre	ss	p	hone #	(781)449-6487	
The National Pe	diculosis A	sso	ciation		
P.O. Box 610189	, Newton, M	IA.	02461		
Health professio	nal Occup	atio	n	Also reported to	
$\mathbf{V}_{\mathrm{yes}}$ \square_{no})			manufacturer	
If you do NOT wa	nt your identi	ty	_	user facility	
disclosed to the ma	nufacturer, p	lace	an 🔳	□distributor	

A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
310	6/95	female	53 lbs
B. Adverse event	or product p	roblem	
Advers	e Event & Pro	duct Proble	em
Outcomes attribut	ted to adverse	event	
death	disability		
☐ life-threatening	□ congenital	anomaly	
hospitalization	□required i	ntervention	
other: extreme	reddness to scal	p(burning)	
Date of event 8/95	5 Dat	e of report	8/11/2000
Describe event or	problem		
The rid made my da	=	xtemely rec	l for two days
to the point that she	-	-	to brush it.
And the smell was j	just not tolerabl	e.	
Relevant tests/labo	oratory data		
Other relevant his	story, includin	g preexisti	ng condition

Triage Unit Sequence #	

<u> </u>				
C. Suspect med	lication(s)			
Name: Rid				
mayonai	se			
Dose, frequency,	, route use	The	rapy d	ates
Rid-once then may		8/7/0	00	to
twice in a two day	period.			8/9/00
Diagnosis for us	e]	Event	abated after use
neither worked!		S	stoppe	d or dose reduced
			doesn	't apply
Lot #	Exp. date]	Event	reappeared after
				oduction
NDC !'			doesn	't apply
NDC# -	-			
Concomitant me	=			
8/10/00-We tried f				
				meister to get the orked well we saw
D. Suspect med			uici W	naca well we saw
-	ncar device	;		
Brand name Type of device				
<u>Hype of device</u> Manufacturer na	me and add	lress	Oper	ator of device
			1 -	ealth professional
			\square_{u}	ser facility
			\square_{d}	istributor
				ration date
model #				
catalog #			If im	planted, give date
serial #			7.0	
lot # other #			If exp	planted, give date
	for ovelve	ion?		
Device available $\square_{\text{yes}} \square_{\text{no}}$			anufact	turer / /
Concomitant me				
	• "			
E. Reporter				
Name and addre	ss	pł	one#	(781)449-6487
The National Pe		드		
P.O. Box 610189	, Newton, M	1 A. 0	2461	
Health profession		patio	n	Also reported to
				manufacturer user facility
If you do NOT was disclosed to the ma	•	•	an 🔳	distributor
mocroscu to the fila	α. α. ται τι, β	iacc i	💷	

A. Patien								
Patient Id	entifier	Date of bir	rth	Sex	Weight			
	307	10/13/1972		female	335	lbs		
B. Advers	se event	or produc	ct pi	oblem				
	Product Problem							
Outcomes	attribut	ted to adve	rse e	event				
\Box_{death}		□disabi	lity					
$\Box_{\text{life-thr}}$	eatening	Conge	nital	anomaly				
$\square_{\mathrm{hospita}}$	alization	\square_{require}	ed in	tervention				
other:								
Date of ev	ent 8/8/	2000	Date	of report	8/9/2	2000		
Describe e	event or							
		t kill lice at	all. U	Jsed lindan	e (the do	ctor		
prescribed	it for me	and my 3 y						
kill the lice	·····							
Relevant t	ests/labo	oratory dat	a					
Other rele	evant his	story, inclu	ding	g preexisti	ng condi	tion		

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: lindane				
Dose, frequency,	route use	The	rapy d	ates
60 ml used once		8/1/0		-
repeated in 7 days		J/ 1/U	,,,	to
		<u> </u>		8/8/00
Diagnosis for us	e			abated after use
lice		S	stoppe	d or dose reduced
			no	
Lot#	Exp. date]	Event	reappeared after
				duction
			VOC	
NDC# -	-		yes	
Concomitant me	dical produ	cts		
D. Suspect med	lical device	•		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
			1 —	ealth professional
				ser facility
			\square_d	istributor
				ration date
model #			Lizyhii	andii aate
moder # catalog #			If im	planted, give date
serial #]	, , ,
lot #			If ext	planted, give date
other #				, a
Device available	for evaluati	ion?	1	
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			anufact	urer//
Concomitant me				
E Danastas				
E. Reporter				(701) 440 5407
Name and addre				(781)449-6487
The National Pe	diculosis A	ssoc	iation	
P.O. Box 610189	, Newton, M	1 A. 0	2461	
Health profession		patio	n	Also reported to
$\mathbf{v}_{\mathrm{yes}}$				manufacturer
If you do NOT war	nt your identi	ity		user facility
disclosed to the ma	-	-	an 🔳	distributor

	-			
A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
302	8-28-95	female	39	lbs
B. Adverse even	t or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ted to adverse e	event		
\Box_{death}	disability			
□ life-threatening	Congenital	anomaly		
hospitalization	_			
other:	<u> </u>			
Date of event 7-2	3-00 Date	of report	8/7/2	2000
Describe event or				
WE STILL HAVE	_	!!!????		
Dolovont tosts/lobe	anatany data			
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng condit	ion
NONE				

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Nix					
KWELL					
Dose, frequency	, route use	The	rapy d	ates	
3-4 TIMES	,	7-23			
o i invido		, 23	, 00	to 8-7-00	
Dia anno air formara	_		E4	abated after use	
Diagnosis for us				abated after use d or dose reduced	
TO GET RID OF	LICE.		stoppe	u of dose feduced	
			no		
Lot#	Exp. date		Event	reappeared after	
			reintro	duction	
			MOC		
NDC# -	-		yes		
Concomitant me	dical produ	cts			
NONE					
D. Suspect med	dical device	•			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
				ealth professional	
			user facility		
				istributor	
			Expir	ration date	
model #					
catalog #			If im	planted, give date	
serial #			•	. , ,	
lot #			If ext	planted, give date	
other #			1	, , ,	
Device available	for evaluati	ion?			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			anufact	urer//	
Concomitant me					
E Domostos					
E. Reporter				(701) 440, 6407	
Name and addre				(781)449-6487	
The National Pe					
P.O. Box 610189		1A. ()2461		
Health professio	_	patio	n	Also reported to	
✓ yes □no)			manufacturer	
If you do NOT wa				user facility	
disclosed to the ma	anufacturer, p	lace	an 🔲	□distributor	

A. Patient Informa			~					
Patient Identifier			Sex	Weight	*1			
290	12/30/91		female	45	lbs			
B. Adverse event or product problem								
Adverse Event & Product Problem								
Outcomes attribut			event					
☐death ☐disability								
	☐ life-threatening ☐ congenital anomaly							
hospitalization	□ requi	red in	ntervention		1			
other:								
Date of event 7/28	3/00	Date	of report	t 7/30/2	2000			
Describe event or peach time (2) Linda sister, and child with with nausea and vor day. I am a nurse a according to the direction of the direct	nne was uso h lice), we miting. thi nd used th ections.	all go is did is pro	ot sick 4-6 subside by	hours later the next	r			
	72413-1							
Other relevant his				ing condi	tion			
No other preexisting	g medical o	condit	ions.					

Triage Unit Sequence #	

once a week for two weeks 7/11/00 to 7/28/ Diagnosis for use lice Event abated afte stopped or dose regyes	er use		
once a week for two weeks 7/11/00 to 7/28/ Diagnosis for use lice Event abated afte stopped or dose regyes	er use		
once a week for two weeks 7/11/00 to 7/28/ Diagnosis for use lice Event abated afte stopped or dose regyes	er use		
Diagnosis for use lice Event abated afte stopped or dose regyes	er use		
Diagnosis for use Event abated afte stopped or dose regions yes	er use		
stopped or dose region yes			
stopped or dose regions yes	advaad		
	eaucea		
	ves		
Lot # Exp. date Event reappeared			
Exp. date Event reappeared reintroduction	arter		
reintroduction			
NDC # yes			
Concomitant medical products			
We used Nox to begin with no symptoms occurred	but		
the lice didn't go away.	, out		
the nee than t go away.			
D. Suspect medical device			
Brand name			
Type of device			
Manufacturer name and address Operator of dev	ice		
l <u> </u>			
user facility	health professional		
distributor			
Expiration date			
model # catalog # If implanted, giv	ve date		
catalog # If implanted, giv serial #	re aute		
	ro doto		
lot # If explanted, giv	e uate		
Device available for evaluation?			
$\square_{\text{yes}} \square_{\text{no}} \square_{\text{returned to manufacturer } _/_$	/		
Concomitant medical products			
-			
E. Reporter			
Name and address phone # (781)449-	6487		
The National Pediculosis Association			
P.O. Box 610189, Newton, MA. 02461			
Health professional Occupation Also repo	rted to		
✓ yes □no □manufa			
If you do NOT want your identity user fac			
ii jou do 1101 want your identity	utor		

A. Patient Inform				
Patient Identifier		Sex	Weight	
276	08-12-1987	female	200	lbs
B. Adverse event	or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ed to adverse o	event		
death	disability			
☐ life-threatening	Congenital	anomaly		
hospitalization	required in	ntervention		
other:				
Date of event 02-2	2000 Date	of report	7/22/20	00
Describe event or		-		
We have been trying	_	lice since I	February. I'	m
an RN, I know how			-	
repeat for newly har				
products because I	don't really wan	t to use Lin	dane.	
Relevant tests/labo	oratory data			
Other relevant his	tory, including	g preexisti	ng conditio	on
	, , , , , , , , ,	, .		

C. Suspect med	dication(s)				
Name: Rid					
Dose, frequency	, route use	The	erapy dates		
as stated on bottle	•	02/2	2000	4-	
			to	06/2000	
Diagnosis for us	e		Event	abate	d after use
head lice			stoppe	d or d	lose reduced
neud nee			doesn'	t ann	lv
Lot#	Exp. date				
Lot #	Ехр. чан				eared after
			reintroduction		
NDC# -	_		doesn'	t appl	ly
Concomitant me	dical produ	cts			
I've also tried Nix	=				
i ve also tried ivix	and Rec.				
D. Suspect med	lical device	•			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator o	of device
			\square_{h}	ealth	professional
				ser fa	
			distributor		
			Expir	ration	date
model #					
catalog #			If im	plant	ed, give date
serial #					
lot #			_ If explanted, give dat		ed, give date
other #					
Device available	_				
yes Ino Concomitant me	returned	to m	anutact	urer	//
Concomitant me	uicai prouu	CIS			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to					reported to
$ \mathbf{V}_{\text{yes}} \square_{\text{no}}$)			l 🗐 n	nanufacturer
If you do NOT want your identity user facility			•		
disclosed to the ma	nufacturer, p	lace	an 🔲	Шd	istributor

	nt Inform					
Patient I	dentifier	Date of bir	th S	Sex	Weight	
	267	11/15/86		female	200	lbs
B. Adve	rse event	or produc	t pro	oblem		
		Adverse	Ever	ıt		
Outcome	s attribut	ted to adver	se ev	ent		
death	ı	disabili	ity			
$\Box_{\text{life-th}}$	nreatening	\Box_{congen}	ital a	nomaly		
\square_{hospi}	talization	require	d int	ervention		
other	: rash upo	n contact				
Date of e	vent 07/1	16/00 I)ate	of report	7/18/2	2000
Describe	event or	problem				
		s spilled upo	9n tl	nis individ	ual while	
	_	reated. A red			_	
		roduct came				in
on her thi	gh the ras	h was almost	inst	antaneous	•	
Relevant	tests/labo	oratory data	1			
Other re	levant bid	story, includ	lina	nreevisti	ng condi	tion
	ed well ov		mg	PICCAISU	ng conti	HOII
rusii iust	ou wen ov	or 5 ms				

Triage Unit Sequence #	

C Sugnast mas	lication(a)				
C. Suspect med	lication(s)				
Name: Rid					
UNK					
Dose, frequency,	route use	The	rapy d	ates	
Once		071	600	4	
				to 071600	
Diagnosis for use	ρ		Event	abated after use	
Head Lice				d or dose reduced	
Head Lice					
			doesn	t apply	
Lot #	Exp. date		Event	reappeared after	
			reintroduction		
**************************************			doesn'	t apply	
NDC# -	-				
Concomitant med	dical produ	cts			
N/A					
D. Suspect med	lical device	•			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			$\square_{\rm h}$	ealth professional	
				ser facility	
			\square_{d}	istributor	
			Expi	ration date	
model #			_		
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
Device available \square_{yes} \square_{no}				uror / /	
Concomitant med	dical produ	cts	anuract	.uiCl//	
	produ				
E. Reporter					
Name and addres	ss	р	hone #	(781)449-6487	
The National Pe		ഥ		. ,	
P.O. Box 610189, Newton, MA. 02461					
Health profession	nal Occup	oatio	n	Also reported to	
\bigvee_{yes} \square_{no}	_			manufacturer	
If you do NOT wai	nt your identi	ty		user facility	
disclosed to the ma			an 🔲	distributor	

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
264	03-12-66	female	135	lbs
B. Adverse event	t or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ted to adverse	event		
death	disability			
☐ life-threatening	□ congenital	anomaly		
hospitalization	required in	ntervention		
other: insanity	!			
Date of event 07/1	12/00 Date	e of report	7/12/2	2000
Describe event or	problem			
Exposed to head lice		-		K
twice, lindane twice straight, combing fo	-			
Sunday night Do I r				
,g		<i>y</i>		
Relevant tests/labo	oratory data			
Other relevant his	= '	g preexisti	ng condit	tion
I am an insulin depe	endent diabetic.			

Triage Unit Sequence #	

C. Suspect med	lication(s)					
Name:						
lindane, Nix, elimite 5%, mayonaise, olive oil, pr						
Dose, frequency,	route use	The	erapy dates			
indane 1% 2X		06/02	2/00	4-		
Nix 1% 2X				to 07/12/00		
Diagnosis for us	e]	Event	abated after use		
nead lice		5	stoppe	d or dose reduced		
			doesn'	t apply		
Lot #	Exp. date]	Event	reappeared after		
		1	reintro	duction		
ATD C. II			doesn'	t apply		
NDC # -	-					
Concomitant me	=					
cannot get rid of						
ife are being ruine						
ny diabetes is tota	-		Ifrom	all the stress.		
D. Suspect med	lical device)				
Brand name						
Type of device			Т_			
Manufacturer na	me and add	lress	1 —	ator of device		
				ealth professional		
user facility						
distributor			istributor			
			Expi	ration date		
nodel #						
catalog #			If im	planted, give date		
serial #						
ot #			If exp	planted, give date		
other #						
Device available yes no			nufact	uror / /		
			anulaci	urci//		
Concomitant medical products						
E. Reporter						
Name and addre	ss	pł	ione #	(781)449-6487		
Γhe National Pe	diculosis A	ssoc	iation			
P.O. Box 610189, Newton, MA. 02461						
Health profession	_	oatio	n	Also reported to		
				manufacturer		
f you do NOT war	-	-		user facility distributor		
lisclosed to the ma	inufacturer, p	lace a	an 🔳	-uisuidutor		

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
263	19/95/	female	42	lbs
B. Adverse even	t or product p	roblem		
Advers	se Event & Prod	luct Proble	em	
Outcomes attribu	ted to adverse o	event		
\Box_{death}	$\Box_{disability}$			
☐life-threatening	Congenital	anomaly		
□ hospitalization	required in	ntervention		
other: bleeding				
Date of event 6/1	7/00 Date	e of report	7/12/20	000
Describe event or	problem			
lice I used Rid, my				
after i put it on. I w	-			
and pulling out her	hair. Her I'm af	aid to try a	nything on	
her head now.				
Relevant tests/lab	oratory data			
Other relevant his	story, including	g preexisti	ng conditi	on
She has asthma			_	
I				

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Rid					
Dose, frequency, route use The			rapy d	ates	
put on hair		7/17	7/00	4	
had a screaming of	child			to 7/17/00	
Diagnosis for us	se		Event abated after use		
lice			stopped or dose reduced		
			no		
Lot#	Exp. date		Event	reappeared after	
			reintroduction		
NDC# -	<u> </u>		doesn'	t apply	
Concomitant me	dical produ	cte			
	=				
none yet i don't k I'm just combing				ıt	
as I can.	nei nair to ge	ı as 1	many Ol	ıı	
	dical davias				
D. Suspect med	aicai device	,			
Brand name					
Type of device		1		-4	
Manufacturer n	ame and add	iress	I —	ator of device	
				ealth professional	
			user facility		
			Шd	istributor	
			Expi	ration date	
model #			- If im	nlantad civa data	
catalog #			- 111 11111	planted, give date	
serial #					
lot # other #			- If exp	planted, give date	
Device available $\square_{ m yes} \ \square_{ m no}$			anufact	urer / /	
Concomitant me					
E. Reporter					
Name and addre	ess	p	hone #	(781)449-6487	
The National Pe	ediculosis A	ssoc	ciation		
P.O. Box 610189, Newton, MA. 02461					
Health professio	-	patio	n	Also reported to	
✓ yes □ _{ne}	-			manufacturer	
If you do NOT wa				user facility	
disclosed to the m	anufacturer, p	lace	an 🔲	□distributor	

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
256	3/4/92	female	60	lbs
B. Adverse event	or product p	roblem		
	Product Prol	olem		
Outcomes attribut	ed to adverse	event		
death	disability			
life-threatening	Congenital	anomaly		
hospitalization	required i	ntervention		
other:				
Date of event 5/00) Dat	e of report	7/7/2	2000
Describe event or	problem			
Has been treated wi			ce prob	lem
continues to exist.	Going on 2 mor	nths now.		
Relevant tests/labo	oratory data			
Other relevant his	story, includin	g preexisti	ng condi	tion
Asthma				

Triage Unit Sequence #	

0.0	!!!!/-\				
C. Suspect med	lication(s)				
Name: Nix					
Lindane					
Dose, frequency	, route use	The	rapy d	ates	
Nix - 4 times		5/00)		
Lindane - once				to 7/6/00	
Diagnosis for us	e		Event	abated after use	
per bottle instruct	ions		stoppe	d or dose reduced	
F			no		
 Lot #	Erm doto	-			
Lot#	Exp. date			reappeared after	
			reintro	oduction	
NDC# -	<u> </u>		yes		
	dical prod	otc.			
Concomitant me	aicai produ	CLS			
D. Cuerred	امما امما				
D. Suspect med	lical device	;			
Brand name					
Type of device			1		
Manufacturer na	ame and add	lress	Oper	ator of device	
			$\square_{\rm h}$	ealth professional	
				ser facility	
				istributor	
			Expi	ration date	
model #			. Te :	-14-4 4-4-	
catalog #			. III IM]	planted, give date	
serial #					
lot #			. If exp	planted, give date	
other #					
Device available □ yes □ no			C		
Concemitent	dical prod-	ιο m	anuract	urer/_/	
Concomitant me	uicai produ	LIS			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to					
$\mathbf{v}_{\mathrm{yes}}$ \square_{no}	_			manufacturer	
f you do NOT want your identity user facility					
			an 🔳	distributor	
disclosed to the ma	anuracturer, p	тасе	an 🔳	- 41541104101	

A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
244	12/7/91	male	60 lbs
B. Adverse event	or product	problem	
Advers	e Event & Pro	oduct Prob	lem
Outcomes attribut	ed to adverse	event	
death	disability	y	
☑ life-threatening	□ congenita	al anomaly	
hospitalization	$\square_{\text{required}}$	intervention	n
other:			
Date of event 1/16	5/00 D a	te of repor	t 7/5/2000
Describe event or		ac of repor	1/3/2000
Grand Mall seizures	=	6/00, 5/4/0	0 and 7/2/00.
All took place withi			
No previous history	with seizures	. Neurologi	st believes this
shampoo is the reas	on.		
Relevant tests/labo	oratory data		
Other relevant his	story, includi	ng preexis	ting condition
None- perfectly hea			-
Never more than a c	cold in 8 years	until this s	tarted this year.

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Nix					
Dose, frequency, route use The			apy d	ates	
1 time for each ev	ent. No	1/5/0	0	to	
follow up given				7/1/00	
Diagnosis for us	e	I	Event	abated after use	
school epidemic		S	stopped or dose reduced		
			yes		
Lot#	Exp. date	ī	Event	reappeared after	
		ı	eintro	oduction	
NDC //		\dashv	yes		
NDC# -	-				
Concomitant me	dical produ	cts			
None					
D. Suspect med	lical device)			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			$\square_{\rm h}$	ealth professional	
				ser facility	
			\square_d	istributor	
			<u> </u>	ration date	
model#			LAPII	ation date	
model # catalog #			If im	planted, give date	
serial #			1	, g	
lot #			If evr	planted, give date	
other #			II CA	Junica, give dute	
Device available	for evaluati	ion?			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			nufact	urer//	
Concomitant me					
E. Reporter					
Name and addre	ss	ph	one #	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occup	pation	n	Also reported to	
$\mathbf{v}_{\mathrm{yes}}$				manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma	-	-	ın 🔲	distributor	

A. Patient Inform			I		
Patient Identifier			Sex	Weight	••
240	12-19-199		female	65	lbs
B. Adverse event					
	e Event & l			em	
Outcomes attribut $\Box_{ m death}$	_		event		
life-threatening	□ disabi	-	alv		
hospitalization			anomaly ntervention		
other: Red/Burn		eu m	itervention	I	
				- 120 K	220
Date of event 05-1 Describe event or		Date	of report	6/30/2	2000
Used the "R.I.D." p suffered a very red a to her, and still it di	roduct on n and burned i dnt work?	head			
	zatory data	•			
Other relevant his				ing condi	tion
she has asthma,and	is allergic to) ma	ny things.		

C. Suspect medication(s)					
Name: Nix	oui.ioi.i(o)				
Name: Nix					
Dose, frequency, route use Therapy dates					
Dose, frequency,				ates	
used it once to wa childrens heads w		05-	10-00	to	
childrens neads w	ıtın			05-11-00	
Diagnosis for us	e		Event abated after use		
To kill lice and ni	ts on scalp.		stopped or dose reduced		
			no		
Lot #	Exp. date		Event	reappeared after	
1	•			duction	
NDC# -	-		yes		
Concomitant me	dical produ	cts	1		
Rid, Nix, Raid ho	use bombs,2a	and 1	l		
flea,lice and tick p				pray for bedding	
and upolstary.		•			
D. Suspect med	lical device	•			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
health professional					
			user facility		
				istributor	
			Expir	ration date	
model #					
			If implanted, give date		
serial #			_		
lot #			_ If exp	planted, give date	
other #	······································				
Device available					
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			anufact	urer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported				Also reported to	
· I I				manufacturer	
If you do NOT want your identity user facility					
lisclosed to the manufacturer, place an distributor					

A. Patient Identifier Date of birth Sex 235 6/29/88 female 110 1bs B. Adverse event or product problem Product Problem Outcomes attributed to adverse event death disability life-threatening congenital anomaly hospitalization required intervention other: Date of event 6/1/00 Date of report 6/25/2000 Describe event or problem I noticed a massive lice presence in my neice's hair. The lindane that the doctor called in did not kill the lice. I found 40 living full grown lice, and not one dead one. All of the immature but hatched lice were living, too. Relevant tests/laboratory data Other relevant history, including preexisting condition There were no medical problems found.					
B. Adverse event or product problem Product Problem Outcomes attributed to adverse event death					
B. Adverse event or product problem Product Problem	Patient Identifier	Date of birth	Sex	Weight	
Outcomes attributed to adverse event death	235	6/29/88	female	110 lt	bs
Outcomes attributed to adverse event death	B. Adverse event	or product p	roblem		
death disability life-threatening congenital anomaly hospitalization required intervention other: Date of event 6/1/00 Date of report 6/25/2000 Describe event or problem I noticed a massive lice presence in my neice's hair. The lindane that the doctor called in did not kill the lice. I found 40 living full grown lice, and not one dead one. All of the immature but hatched lice were living, too. Relevant tests/laboratory data Other relevant history, including preexisting condition		Product Prob	lem		
life-threatening congenital anomaly hospitalization required intervention other: Date of event 6/1/00 Date of report 6/25/2000 Describe event or problem I noticed a massive lice presence in my neice's hair. The lindane that the doctor called in did not kill the lice. I found 40 living full grown lice, and not one dead one. All of the immature but hatched lice were living, too. Relevant tests/laboratory data Other relevant history, including preexisting condition	Outcomes attribut	ed to adverse e	event		
hospitalization other: Date of event 6/1/00 Date of report 6/25/2000 Describe event or problem I noticed a massive lice presence in my neice's hair. The lindane that the doctor called in did not kill the lice. I found 40 living full grown lice, and not one dead one. All of the immature but hatched lice were living, too. Relevant tests/laboratory data Other relevant history, including preexisting condition	death	disability			
hospitalization other: Date of event 6/1/00 Date of report 6/25/2000 Describe event or problem I noticed a massive lice presence in my neice's hair. The lindane that the doctor called in did not kill the lice. I found 40 living full grown lice, and not one dead one. All of the immature but hatched lice were living, too. Relevant tests/laboratory data Other relevant history, including preexisting condition	□ life-threatening	Congenital	anomaly		
Date of event 6/1/00 Date of report 6/25/2000 Describe event or problem I noticed a massive lice presence in my neice's hair. The lindane that the doctor called in did not kill the lice. I found 40 living full grown lice, and not one dead one. All of the immature but hatched lice were living, too. Relevant tests/laboratory data Other relevant history, including preexisting condition	hospitalization				
Describe event or problem I noticed a massive lice presence in my neice's hair. The lindane that the doctor called in did not kill the lice. I found 40 living full grown lice, and not one dead one. All of the immature but hatched lice were living, too. Relevant tests/laboratory data Other relevant history, including preexisting condition	other:	<u> </u>			٦
I noticed a massive lice presence in my neice's hair. The lindane that the doctor called in did not kill the lice. I found 40 living full grown lice, and not one dead one. All of the immature but hatched lice were living, too. Relevant tests/laboratory data Other relevant history, including preexisting condition	Date of event 6/1/	00 Date	of report	6/25/200	00
I noticed a massive lice presence in my neice's hair. The lindane that the doctor called in did not kill the lice. I found 40 living full grown lice, and not one dead one. All of the immature but hatched lice were living, too. Relevant tests/laboratory data Other relevant history, including preexisting condition	Describe event or	problem			
40 living full grown lice, and not one dead one. All of the immature but hatched lice were living, too. Relevant tests/laboratory data Other relevant history, including preexisting condition			my neice's	hair. The	
Relevant tests/laboratory data Other relevant history, including preexisting condition					d
Relevant tests/laboratory data Other relevant history, including preexisting condition				All of the	
Other relevant history, including preexisting condition	immature but hatche	ed lice were livii	ng, too.		
Other relevant history, including preexisting condition					
Other relevant history, including preexisting condition					
Other relevant history, including preexisting condition					
Other relevant history, including preexisting condition					
Other relevant history, including preexisting condition					
Other relevant history, including preexisting condition					
Other relevant history, including preexisting condition					
Other relevant history, including preexisting condition					
Other relevant history, including preexisting condition	Dolovant tasts/labo	rotory doto			
	Kelevant tests/labo	natory data			
	Othon wolonous 1.1		- nuna!1	na oor 3:4°	
There were no medical problems found.				ng conaitio	n
	There were no medi	icai problems to	una.		

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: lindane					
Dose, frequency	Dose, frequency, route use Therapy dates				
1 dose first week,	1 dose	6/1/	00		
second week				to 6/9/00	
Diagnosis for us	e		Event	abated after use	
?			stoppe	d or dose reduced	
			no		
Lot#	Exp. date		Event	reappeared after	
				duction	
			VAC		
NDC# -	-		yes		
Concomitant me	dical produ	cts			
We did the mayor	naisse treatm	ent a	and I fo	und only 3 nits. I	
had found thousa	nds the first o	day,	and hur	ndreds the next.	
D. Suspect med	dical device)			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
			\square_{h}	ealth professional	
				ser facility	
				istributor	
				ration date	
model #			Lipi	auton dute	
catalog #			If im	planted, give date	
serial #			- '	. , ,	
lot #			If ext	planted, give date	
other #				granicou, gry e unico	
Device available	for evaluati	ion?	-		
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$				urer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	ss	p	hone #	(781)449-6487	
The National Pe	diculosis A	sso	ciation		
P.O. Box 610189	, Newton, M	1A. (02461		
Health professio	nal Occup	oatio	n	Also reported to	
	_	-		manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma			an 🔲	$\square_{ m distributor}$	

A. Patient Informa			~					
Patient Identifier		rth	Sex		eight			
234	08/21/75		male		65	lbs		
B. Adverse event								
	Adverse							
Outcomes attributed to adverse event								
death	∐disabi □	•	_					
□ life-threatening			anomal					
hospitalization			iterventi	ion				
other: terminal l	brain cancei	r						
Date of event 10/0	01/1994	Date	of rep	ort	6/25/2	2000		
In a correctional factinstructed to leave lexperienced burning sores and scabs as a	ice treatme & peeling of result.	nt or	oVER	NIGI	IT. Th	iey		
Other relevant his Now, six years later tumor. My son was an othe	, my son is	dyin	g of a n	nalign	ant brai			

C. Suspect med	lication(s)					
Name: lindane						
Possibly	Kwell					
Dose, frequency		The	erapy dates			
They admitted mi			/2000	aces		
wrong. Applied o		1/10	/2000	to		
		1.	-	6/26/2000		
Diagnosis for us				abated after use		
Lice and/or scabie	S	1	stoppe	d or dose reduced		
			doesn'	t apply		
Lot #	Exp. date]	Event	reappeared after		
]	reintro	duction		
ND C #			doesn'	t apply		
NDC# -	-					
Concomitant me	-					
Chemo wafers we	•					
and followed up v	vith six week	s of	radiatio	on treatments.		
D. Suspect med	lical device)				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
			\square_{h}	ealth professional		
			user facility			
			\square_d	istributor		
			Expir	ration date		
model #						
catalog #			If im	planted, give date		
serial #						
lot #			If exp	olanted, give date		
other #				, , ,		
Device available	for evaluati	ion?				
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to m	anufact	urer/_ /		
Concomitant me	dical produ	cts				
E. Reporter						
Name and addre	ss	nl	hone #	(781)449-6487		
Name and address phone # (781)449-6487 The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
Health professio	nal Occup	atio	n	Also reported to		
$ \mathbf{V}_{\text{yes}} \square_{\text{no}} $	_			manufacturer		
If you do NOT wa	nt your identi	ity		user facility		
disclosed to the manufacturer, place an distributor						

A Bationt I	f a was							
A. Patient II								
		Date of birth	Sex	Weight				
	230	6-16-90	female	66	lbs			
B. Adverse	event	or product p						
		Product Prol	olem					
_	ttribut	ted to adverse	event					
□death	□ death □ disability							
□ life-threa	tening	Congenital	anomaly					
$\square_{\text{hospitali}}$	zation	□ _{required} i	ntervention					
other:								
Date of even	nt 6-10	0-2000 Dat	e of report	6/23/2	2000			
Describe eve	ent or							
lice still craw								
Relevant tes	ts/labo	oratory data						
Other releva	ant his	story, includin	g preexisti	ng condi	tion			

Triage Unit Sequence #	

C Suchaat mad	lication(s)				
C. Suspect med	ilcation(5)				
Name: Nix					
kwell					
Dose, frequency,	, route use	The	rapy d	ates	
been doing heads	every 2	2-20	000	to	
weeks for months				to 6-2000	
Diagnosis for us	e		Event :	abated after use	
head lice			stopped or dose reduced		
neud nee					
T 4 11	D 14			t apply	
Lot#	Exp. date			reappeared after	
			reintroduction		
NDC# -			doesn'	t apply	
Concomitant me	dical produ	cts			
D. Suspect med	lical device	•			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			\square_{h}	ealth professional	
				ser facility	
				istributor	
			Expi	ration date	
model #			*		
catalog #			If im	planted, give date	
serial #			-		
lot #			If ext	olanted, give date	
other #			1	, , ,	
Device available	for evaluati	ion?			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			anufact	urer//	
Concomitant me	dical produ	cts			
E Damantan					
E. Reporter				(=04) 440 440=	
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported				Also reported to	
)			manufacturer	
f you do NOT want your identity user facility					
disclosed to the ma			an 🔲	distributor	

A. Patient Ir	eform	otion						
		Date of birth	G	TT7. * . 1. 4				
	itifier 226	Date of birth 01/19/90	Sex female	Weight 100 lbs				
		t or product		100 108				
D. Auverse	eveni	Product Pro						
Outcomes at	tribut							
death	Outcomes attributed to adverse event Outcomes attributed to adverse event death disability							
	life-threatening congenital anomaly							
hospitali	_		intervention					
other: no								
Date of even	t 04/1	16/00 Da	te of report	6/18/2000				
Describe eve	ent or							
		ive for the trea	tment of hea	ıd lice				
Relevant tes	ts/labo	oratory data						
Í								
Other releva	ant his	story, includi	ng preexisti	ng condition				
I								

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: lindane					
1%					
Dose, frequency,	route use	The	rapy d	ates	
standard		050	500		
otali d		000		to 061700	`
D:			T		
Diagnosis for us	e			abated after	
lice			stopped or dose reduced		
			doesn'	t apply	
Lot#	Exp. date		Event 1	reappeared a	ıfter
				duction	
NDC# -	-		aoesn'	t apply	
Concomitant me	dical produ	cts			
D. Suspect med	lical device	<u>, </u>			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of devic	e
				ealth professi	
				ser facility	Onai
				istributor	
				ration date	
3 3 //			LAPII	ation date	
model # catalog #			- If im	planted, give	date
catalog # serial #			- ,	r, 8	
lot #			If evr	olanted, give	date
other #					aute
Device available	for evaluati	or?	1		
$\square_{\text{yes}} \square_{\text{no}}$				urer / /	
Concomitant me					
E. Reporter					
Name and addre	SS	p	hone #	(781)449-64	187
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported					
$\mathbf{v}_{\mathrm{yes}} \square_{\mathrm{no}}$)			manufac	turer
If you do NOT was	nt your identi	ty		user faci	•
disclosed to the ma	nufacturer, p	lace	an 🔲	□distribut	or

A. Patient Inform								
Patient Identifier	Date of birth	Sex	Weight					
221	3/3/89	female	125	lbs				
B. Adverse event	or product p	roblem						
	Product Prob	lem						
Outcomes attributed to adverse event								
death disability								
☐ life-threatening ☐ congenital anomaly								
hospitalization								
other:								
Date of event 11-9	99 Date	of report	6/12/2	2000				
Describe event or	problem							
Have been trying ur	-	-						
every over-the-coun								
mayo!! Affects both my son 4. Don't kn			sn't bother					
illy soil 4. Doilt kii	iow what else ic	uo.						
Relevant tests/labo	oratory data							
Other relevant his	story including	nreevisti	ng condi	tion				
Other relevant ms	, tory, merading	g pi cexisti	ng condi	1011				

Triage Unit Sequence #	

C. Suspect me	edication(s)			
Name:				
have tri	ed everything			
Dose, frequenc	y, route use	The	rapy d	ates
***		0-00)	
				to 0-00
Diagnosis for u	se		Event	abated after use
****		ĺ	stoppe	d or dose reduced
			no	
Lot #	Exp. date		E4	
200 11	Zapi uute			reappeared after oduction
			i cinti (duction
NDC# -	-		yes	
Concomitant m	edical produ	cts		
D. Suspect me	edical device	•		
Brand name				
Type of device				
Manufacturer i	name and add	lress	1 —	ator of device
				ealth professional
				ser facility
			_	istributor
			Expi	ration date
model #			If im	planted, give date
catalog # serial #			. 11 1111	pianicu, give uaic
lot #			If ex	olanted, give date
other #				siantea, give date
Device availabl	e for evaluat	ion?		
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned		anufact	turer/_/
Concomitant m	edical produ	cts		
E. Reporter				
Name and addr	ess	pì	hone #	(781)449-6487
The National P		드		,
P.O. Box 61018				
Health professi				Also reported to
$\mathbf{V}_{\text{yes}} \square_{\text{r}}$		yatiO	*11	manufacturer
If you do NOT w		itv		user facility
disclosed to the n	-	-	an 🔲	distributor

A - Bationt Inform							
A. Patient Inform							
Patient Identifier		Sex	Weight				
218	07/22/88	female	83 lbs				
B. Adverse even							
0	Product Prob						
_	Outcomes attributed to adverse event						
□ death	☐ disability						
I —	☐ life-threatening ☐ congenital anomaly						
hospitalization	□ required in	ntervention	1				
other:							
Date of event 02/	00/ Date	e of report	6/9/2000				
Describe event or We used the follow lice:Nix,Rid, and Qu	ing products and uell.	l continued	to find live				
Relevant tests/labo		g preexisti	ng condition				

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Nix		_			
Kwell,Rid					
Dose, frequency, route use Therapy dates					
unsure of dose,use	ed each once	02/0	00	to	
				to 06/00	
Diagnosis for us	e		Event	abated after use	
live lice			stopped or dose reduce		
			no		
 Lot #	Exp. date			7 0:	
Lot π	Ехр. чан			reappeared after	
			reintro	oduction	
NDC# -	-		yes		
Concomitant me	dical produc	cts			
	arour produc				
D. Suspect med	dical device	,			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
				ealth professional	
				ser facility	
				istributor	
			Expi	ration date	
model #					
catalog #			If im	planted, give date	
serial #			- L		
lot #			_ If exp	planted, give date	
other #					
Device available $\square_{yes} \square_{no}$				turer / /	
Concomitant me					
	-				
E. Reporter					
Name and addre	ss	p	hone #	(781)449-6487	
The National Pe	diculosis A	sso	ciation		
P.O. Box 610189	, Newton, M	ΙΑ. (02461		
Health professio	nal Occup	oatio	n	Also reported to	
$\mathbf{V}_{\mathrm{yes}}$ \square_{no})			manufacturer	
If you do NOT wa	nt your identi	ity]	user facility	
disclosed to the ma	anufacturer, p	lace	an 🔳	□distributor	

A. Patient						
Patient Id	entifier	Date of birt	h Se	X	Weight	
	216	02/17/97	fe	male	29	lbs
B. Advers	se event	or product	prob	lem		
	Advers	e Event & Pi	oduci	Proble	em	
Outcomes	attribut	ted to advers	e eve	nt		
\Box_{death}		disabili	ty			
□ _{life-thr}	eatening	\Box_{congeni}	tal and	maly		
	alization	required		-		
		g nape of nec				
Date of ev				report	6/4/2	2000
			<u> </u>	тероге	0/4/2	.000
Describe e Used Nix t		ead & combe	l with	nit cor	nh Next d	av
		ng & has a ra				
		e lice in her h		-	-	
	_	or lice daily.		•	U	
		•				
Relevant t	ests/labo	oratory data				
Other rele	evant his	story, includ	ing p	reexisti	ng condit	tion
		• /	•		J	

Triage Unit Sequence #	

C. Suspect medication(s)						
Name: Nix						
Dose, frequency,	route use	The	erapy dates			
1 treatment & con	nbed out	06/0	01/00			
with metal comb.			to 06/01/00			
Diagnosis for us	<u>е</u>		Event abated after use			
doctor advised to			stopped or dose reduce			
directions.	iono ii peng		doesn't apply			
Lot #	Exp. date					
Lot π	Ехр. чан		Event reappeared after reintroduction			
			reintroduction			
NDC# -	-		doesn't apply			
Concomitant me	dical produ	cts				
	•					
D. Suspect med	lical device	•				
Brand name						
Type of device						
	me and add	lress	S Operator of device			
	health professional					
user facility						
distributor						
Expiration d			Expiration date			
model #						
catalog #			If implanted, give date			
	serial #					
lot #			_ If explanted, give date			
other #						
Device available □ _{ves} □ _{no}						
yes no returned to manufacturer / / Concomitant medical products						
Concommant IIIC		cts				
Concomitant me		cts				
E. Reporter		cts				
	dical produ		shone # (781)449-6487			
E. Reporter Name and addre The National Pe	dical produ ss diculosis A	p	Shone # (781)449-6487 ciation			
E. Reporter Name and addre	dical produ ss diculosis A	p	Shone # (781)449-6487 ciation			
E. Reporter Name and addre The National Pe P.O. Box 610189 Health professio	ss diculosis A , Newton, M	p ssoc IA. (ciation 02461 Also reported t			
E. Reporter Name and addre The National Pe P.O. Box 610189	ss diculosis A , Newton, M nal Occup	p SSSOC IA. (patio	Shone # (781)449-6487 ciation 02461			

A. Patient Inform	ation				
Patient Identifier	Date of birth	Sex	Weight		
215	03/05/65	male	11	lbs	
B. Adverse event	or product p	roblem			
	Product Prob	lem			
Outcomes attribut	ed to adverse	event			
death	disability				
☐ life-threatening	Congenital	anomaly			
hospitalization	required in	ntervention			
other:					
Date of event 24/0	05/00 Date	e of report	6/3/2	2000	
Describe event or	problem				
HAVING TROUB	LE GET RUD (OF LICE F	ROM MY		
KIDS HEAD					
Relevant tests/laboratory data					
Other relevant his	tory including	n nroovisti	na condit	tion	
Other relevant his	otory, including	g preexisti	ng condi	uon	

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name: malathio				
	YCLEAR			
Dose, frequency, route use The			rapy d	ates
ABOUT THREE	TIMES	24/0	5/00	to
EACH ONE				3/6/00
Diagnosis for us	e		Event	abated after use
N/A			stoppe	d or dose reduced
- "			no	
 Lot #	Exp. date			
Lot#	Exp. date			reappeared after
			reintro	oduction
NDC# -		-	no	
	diaal reside	ot c		
Concomitant me	uicai produ	CLS		
D. Suspect med	lical device)		
Brand name				
Type of device			1	
Manufacturer na	ame and add	lress		ator of device
				ealth professional
				ser facility
			Шd	istributor
			Expi	ration date
model #			- 10.	
catalog #			. If im	planted, give date
serial #				
lot #			- If exp	planted, give date
other #				
Device available				
Uyes Uno				urer/_/
Concomitant me	uicai produ	LIS		
E. Reporter				
Name and addre	SS	p	hone #	(781)449-6487
The National Pe	diculosis A	ssoc	ciation	
P.O. Box 610189, Newton, MA. 02461				
Health professio	nal Occup	oatio	n	Also reported to
$\mathbf{\nabla}_{\mathrm{yes}}$ \square_{no}	_			manufacturer
If you do NOT wa	nt your identi	ity		user facility
disclosed to the ma			an 🔲	distributor

A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
212	03-16-95	female	45	lbs
B. Adverse event	or product p	roblem		
Advers	e Event & Prod	luct Proble	em	
Outcomes attribut	ted to adverse o	event		
\Box_{death}	disability			
☐ life-threatening	Congenital	anomaly		
hospitalization	_			
other: broke ou				
Date of event 05/0	00/ Date	e of report	5/29/20	00
Describe event or	problem			
Used RID & it brok	=	neck real b	oig bumps &	ż
didn't kill lice,she h	ad to go to Dr.fo	or this also	had a shot o	of
antibiotic and got ar			med's. wor	k
for head lice even p	rescription all is	very bad.		
Relevant tests/labo	oratory data			
Other relevant his	story including	nreevisti	ng conditi	or
Asthma	, tory, meraum,	g pi cexisti	ng conditio	711

Triage Unit Sequence #	

C. Suspect me	dication(s)			
Name: Rid				
Dose, frequency	, route use	The	erapy d	ates
on hair for 10 mir	1	05/0	00	
				to 05/00
Diagnosis for us	se	<u> </u>	Event	abated after use
lice				d or dose reduced
			no	
 Lot #	Exp. date			1 - 64
Lot "	Exp. uate			reappeared after oduction
			гениго	duction
NDC# -	-		yes	
Concomitant me	dical produ	cts		
Nix April	<u>*</u>			
Lindaine Shampo	o March			
•				
D. Suspect med	dical device	9		
Brand name				
Type of device				
Manufacturer n	ame and add	lres	s Oper	ator of device
			\square_{h}	ealth professional
			\square_{u}	ser facility
			\square_{d}	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #			-	
lot #			_ If exp	planted, give date
other #				
Device available				
$\square_{\text{yes}} \square_{\text{no}}$				urer/_/
Concomitant me	edical produ	cts		
E. Reporter				
Name and addre	ess	p	hone #	(781)449-6487
The National Pe	ediculosis A	sso	ciation	
P.O. Box 610189	, Newton, M	IA.	02461	
Health professio	nal Occuj	patio	n	Also reported to
$\mathbf{v}_{\mathrm{yes}}$	_			manufacturer
If you do NOT wa	nt your ident	ity		user facility
disclosed to the m			an 🔲	□distributor

A. Patient Inform	ation					
Patient Identifier		g orr	Waisht			
208	10/07/87	Sex female	Weight 124 lbs			
B. Adverse event			121 100			
	e Event & Prod		em			
Outcomes attribut	ted to adverse e	event				
□death	disability					
☐ life-threatening	_	anomaly				
hospitalization		ntervention				
other: loss of ha						
Date of event 06/9	96/ Date	of report	5/22/2000			
Describe event or	i					
after several uses h		g out by the	e hand full			
		,				
Relevant tests/laboratory data						
Other relevant history, including preexisting condition						
		- -	J			

Triage Unit Sequence #	

C. Suspect me	dication(s)				
Name: Rid					
Mayo, Clear, Nix, Olive oil,					
Dose, frequency, route use The			erapy dates		
recommended do	sageused	06/96	<u> </u>		
every ten days	C			to 05/00	
Diagnosis for u	Se Se	F	Event :	abated after use	
over the counter			stopped or dose reduce		
over the counter	products				
T - 4 #	II 1.4.		no		
Lot#	Exp. date			reappeared after	
		r	reintroduction		
NDC# -			yes		
Concomitant m	edical produ	ets			
Concomitant III	cuicai pi ouu	LIS			
D. Suspect me	dical device)			
Brand name					
Type of device			1		
Manufacturer n	ame and add	lress	Oper	ator of device	
				ealth professional	
			user facility		
			\square_{d}	istributor	
			Expir	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	olanted, give date	
other #				•	
Device available	e for evaluati	ion?			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to ma	nufact	urer/_/	
Concomitant m	edical produ	cts			
E. Reporter					
Name and addr	occ	nh	one #	(781)449-6487	
The National P		<u> </u>		(761)++7-0+67	
P.O. Box 61018					
			Also reported to		
				manufacturer	
If you do NOT want your identity					
disclosed to the m	anufacturer, p	lace a	n 🔲	□distributor	

	000011						
A. Patient Inform	ation						
Patient Identifier	Date of birth	Sex	Weight				
204	06/20/1990	female	118	lbs			
B. Adverse event	or product p	roblem					
	Product Prob	olem					
Outcomes attribut	ed to adverse	event					
death	disability						
☐ life-threatening							
hospitalization	□required in	ntervention	1				
other:							
Date of event 03/2	20/00 Dat	e of report	5/20/2	000			
Describe event or							
I have used so many	=	C and preso	cribed.				
Nothing works.							
Relevant tests/labo	oratory data						
Other relevant his	story, includin	g preexist	ing condit	ion			
My husband and yo				A			
I have a friend whose			d he never				
gets them either. Co	outa unis de a fa	ctor					

C. Suspect medication(s)					
Name: Nix					
Rid, Lice Free, Pronto, Lindane					
Dose, frequency, route use Therapy dates			ates		
As instructed		03/2	03/2000		
			to 05/2000		
Diagnosis for us	e		Event	abated after use	
_			d or dose reduced		
Lice infestation					
	l		doesn	t apply	
Lot#	Exp. date		Event reappeared afte		
			reintroduction		
NDC #			doesn'	t apply	
NDC# -	-			·	
Concomitant me	dical produ	cts			
06/1999					
D. Suspect med	dical device)			
Brand name					
Type of device			1		
Manufacturer na	ame and add	lress		ator of device	
				ealth professional	
			user facility		
			\Box_{d}	istributor	
			Expi	ration date	
model #			_		
catalog #			- If im	planted, give date	
serial #			-		
lot #			_ If exp	planted, give date	
other #					
Device available $\square_{ m yes} \ \square_{ m no}$				urer / /	
Concomitant me	dical produ	cts			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pe	diculosis A	sso	ciation		
P.O. Box 610189	, Newton, M	IA.	02461		
Health professio	nal Occup	oatio	n	Also reported to	
\bigvee_{yes} \square_{no}	_			manufacturer	
If you do NOT want your identity user facility					
disclosed to the manufacturer, place an distributor					

A. Patient Inforn						
Patient Identifier	Date of bir	rth S	Sex	Weight		
203	12-24-60		female	140	lbs	
B. Adverse event or product problem						
	Product I	Probl	em			
Outcomes attribu	ited to adve	rse ev	vent			
death	□disabi	lity				
☐ life-threatening	g \square_{conger}	nital a	nomaly			
hospitalization			ervention			
other:						
Date of event 05	-01-2000	Date	of report	5/17/2	2000	
Describe event or						
Resistant head lice	=	and K	well shan	ipoos.		
Trying olive oil and	d combing bu	ut stil	l finding li	ve lice. M		
daughter got lice fr						
helped her but mo	m got them	.Wou	ld total co	oloring he	lp?	
D.1	4 1.4	_				
Relevant tests/laboratory data						
Other relevant hi	istory, inclu	ding	preexisti	ng condi	tion	

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: Nix					
Dose, frequency, route use The			erapy dates		
nix used several ti	mes	3/1/	2000	to	
				5/1/2000	
Diagnosis for us	se		Event abated after use		
head lice			stopped or dose reduce		
			no		
Lot#	Exp. date		Event	reappeared after	
	-			duction	
NDC# -	-		no		
Concomitant me	dical produ	cts			
rid 3/1/2000 Kwe	11 2/1/2000	Olive	oil trea	tments being used	
at present					
D. Suspect med	dical device)			
Brand name					
Type of device					
Manufacturer n	ame and add	lress	Oper	ator of device	
				ealth professional	
			user facility		
			distributor		
			Expi	ration date	
model #			T.C :	ulantad aina data	
catalog #			- III IM	planted, give date	
serial #					
lot # other #			_ If explanted, give date		
Device available	for evaluat	ion?			
$\square_{\text{yes}} \square_{\text{no}}$			anufact	curer / /	
Concomitant me					
E. Donostor					
E. Reporter					
Name and addre		Ĺ	hone #	(781)449-6487	
The National Pediculosis Association					
	P.O. Box 610189, Newton, MA. 02461				
				Also reported to	
<u> </u>			manufacturer		
If you do NOT want your identity disclosed to the manufacturer, place an distributo			distributor		
disclosed to the m	amuracturer, p	race	ali 🔳	GISH IUUIUI	

A. Patient Inform			
Patient Identifier		Sex	Weight
198	4/17/89	female	56 lbs
B. Adverse event			
	Product Prob	olem	
Outcomes attribut	_	event	
death	disability		
☐ life-threatening	Congenital	anomaly	
□hospitalization	required in	ntervention	1
other:			
Date of event 19/9	93/ Dat	e of report	5/14/2000
Describe event or	problem		
Recurrant head lice	_		-
(Male, DOB 5/7/19	64 & Female D	OB 1/13/19	954).
Relevant tests/labo	oratory data		
Other relevant his	story, includin	g preexist	ing condition
From 1993 to the pr			
of head lice, includi			
for over two years. individuals have lon		given up.	All three
marviduais nave ion	ig of tiller half.		

C. Suspect medication(s)					
Name: Kwell					
Dose, frequency, route use The			erapy dates		
Used as directed of	n label and	1995	5		
by doctor				to 1998	
Diagnosis for us	e]	Event abated after use		
Head lice		:	stoppe	d or dose reduced	
			doesn'	t apply	
Lot #	Exp. date	Ī	Event 1	reappeared after	
			reintroduction		
NDC #			doesn'	t apply	
NDC# -	-				
Concomitant me	dical produ	cts			
Nix, Rid, tea tree	oil. Frequen	t use,	, over h	ter course of	
several years.					
D. Suspect med	dical device)			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
			\square_{he}	ealth professional	
			user facility		
			distributor		
			_	ation date	
model#			Expii	ation date	
model # catalog #			If im	planted, give date	
serial #			· '	,, g	
lot #			If ovr	planted, give date	
other #			III CAP	nanteu, give uate	
Device available	for evaluati	ion?			
$\square_{\text{yes}} \square_{\text{no}}$			anufact	urer / /	
Concomitant me					
E. Reporter					
Name and address phone # (781)449-6487					
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	1 A. 0	02461		
Health professio	nal Occup	atio	n	Also reported to	
✓ yes □no □ manufacturer					
If you do NOT want your identity user facility					
disclosed to the ma	-	-	an 🔲	□distributor	

A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
197	12/10/93	female	52	lbs
B. Adverse event	or product p	roblem		
	Product Prob	lem		
Outcomes attribut	ted to adverse e	event		
\Box_{death}	disability			
□ life-threatening	Congenital	anomaly		
hospitalization				
other:				
Date of event 5/12	2/00 Date	of report	5/13/20	000
Describe event or		оттероге	5, 15, 2	000
Apparent resistance		Nix and ne	rmethrin 5	%
resulting in prescrip				. • ,
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng conditi	ion

Triage Unit Sequence #	

C. Suspect med	dication(s)					
	ilcation(s)					
Name: Nix						
T						
Dose, frequency		The	rapy d	ates		
1 1/2 oz, 1st & 4t	h day	5/5/	00	to		
				5/12/00		
Diagnosis for use Event abated after use						
Massage thorough	nly into scal) .	stoppe	d or dose reduced		
	,		doesn'	t apply		
Lot #	Exp. date					
Lot "	Exp. date			reappeared after		
			reintro	duction		
NDC# -	_		doesn'	t apply		
Concomitant me	dical produ	otc				
	=			1 . 10/ 1		
7th day, permethr						
oz.The lice are no						
dangers of lindan			л бу шу	doctor. I was		
D. Suspect medical device						
Brand name						
Type of device			_			
Manufacturer na	ame and add	lress	Oper	ator of device		
			\square_{h}	ealth professional		
				ser facility		
			\square_{d}	istributor		
			Expir	ration date		
model #			•			
catalog #			If im	planted, give date		
serial #			-			
lot #			If ext	planted, give date		
other #				, g		
Device available	for evaluati	ion?				
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$				urer / /		
Concomitant me						
E. Reporter						
Name and addre			1 4	(701)440 (407		
		ᆫ		(781)449-6487		
The National Pe						
P.O. Box 610189				T.2		
Health professio	- 1	patio	n	Also reported to		
v _{yes} □ _{no})			manufacturer		
If you do NOT wa	nt your identi	ity]	user facility		
disclosed to the ma	anufacturer, p	lace	an 🔳	□distributor		

A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
194	1/10/92	female	50 lbs
B. Adverse event	t or product p	roblem	
	Product Prob	lem	
Outcomes attribut	ted to adverse e	event	
\Box_{death}	disability		
☐ life-threatening	□ congenital	anomaly	
□hospitalization	required in	ntervention	
other:			
Date of event 19/9	96/ Date	of report	5/10/2000
Describe event or			
I treated all three of		indane loti	on (Qwell)
from the doctor and			
treatments only to h	nave the lice retu	ırn.	
Relevant tests/labo	oratory data		
Other relevant his	story, including	g preexisti	ng condition
			J

C. Suspect med	lication(s)					
Name: Kwell						
Nix, mayo, olive oil, lindane, pronto, sprays, etc						
Dose, frequency,	route use	The	rapy d	ates		
I followed contain	er	199	6	to		
instructions				to 2000		
Diagnosis for us	e		Event	abated after use		
Head lice			stoppe	d or dose reduced		
			doesn'	t apply		
Lot #	Exp. date		Event	reappeared after		
	•			oduction		
NDC# -			doesn'	t apply		
	Jimal are 2	n4 c:				
Concomitant me	aicai produ	cts				
D. Suspect med	lical device	•				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
				ealth professional		
				ser facility		
			\sqcup_{d}	istributor		
			Expi	ration date		
model #						
catalog #			If im	planted, give date		
serial #						
lot #			If ext	planted, give date		
other #				,, <u>a</u>		
Device available	for evaluati	ion?	<u> </u>			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$				urer//		
Concomitant me						
E. Reporter						
Name and addre	ss	p	hone #	(781)449-6487		
The National Pe	diculosis A	sso	ciation			
P.O. Box 610189	, Newton, M	IA.	02461			
Health professio	nal Occup	oatio	n	Also reported to		
$\mathbf{\nabla}_{\mathrm{yes}}$ $\mathbf{\square}_{\mathrm{no}}$	-			manufacturer		
If you do NOT was	nt vour identi	tx/		user facility		
disclosed to the ma			an 🔲	distributor		
arserosea to the III8	muraciurer, p	iace	α11 <u></u>	3333704101		

A Builton (Info					
A. Patient Infor					
Patient Identific	er Date of	birth	Sex	Weight	
192	11-30-0		female	48	lbs
B. Adverse eve	nt or prod	luct pr	oblem		
	Produc	t Prob	lem		
Outcomes attrib	uted to ad	verse e	vent		
\Box_{death}	\Box_{disa}	bility			
□life-threatenin	ng \square_{con}	genital	anomaly		
hospitalizatio			tervention		
other:					
Date of event 03	5/04/00	Date	of report	5/8/2	000
Describe event of			F		
04/24 treat with F	_				
04/26/treat with N		ig to nu	ırse-60 min	ı	
05/03 treat with N		-			
05/03 again accd					
05/04 Dr. presc L	indane				
Relevant tests/la	horatory d	ata			
rece vant tests/la	boratory a				
Other relevant l	nistory, inc	cluding	g preexisti	ng condit	ion
none					

Triage Unit Sequence #	

C. Suspect med	ilcation(5)				
Name: Rid					
Nix 1%					
Dose, frequency	, route use	The	rapy d	ates	
Rid once, Nix 3 ti	mes,	04/2	24/00		
Lindane once	indane once to 05/04/00				
Diagnosis for us	e		Event	abated after use	
Head lice that just	wouldn't gi	ve	stoppe	d or dose reduced	
up			doesn'	t apply	
Lot#	Exp. date		Event	reappeared after	
			reintro	duction	
NDC# -	-		doesn'	t apply	
Concomitant me	dical produ	cts			
	=		were tri	ed. I never would	
				et rid of them was	
				to say that at least	
D. Suspect med	dical device	е			
Brand name					
Type of device					
Manufacturer na	me and ad	dres	Oper	ator of device	
			\square_{h}	ealth professional	
				ser facility	
			\square_{d}	istributor	
			Expi	ration date	
model #					
catalog #			- If im	planted, give date	
serial #			-		
lot #			_ If exp	olanted, give date	
other #]		
Device available				, ,	
$\square_{\text{yes}} \square_{\text{no}}$			anufact	urer//	
Concomitant me	aicai proau	cts			
E. Reporter					
Name and addre	ss	p	hone #	(781)449-6487	
The National Pe					
P.O. Box 610189	, Newton, N	/ΙΑ. (02461		
Health professio ✓ yes □ no		patio	on	Also reported to manufacturer	
If you do NOT wa		itv		user facility	
disclosed to the ma	•	•	an 🔲	distributor	
	, [

A. Patient	Inform	ation				
Patient Ide	ntifier	Date of b	irth	Sex	Weight	
	191	09-27-95	5	female	45	lbs
B. Adverse	e event	or produ	uct pi	roblem		
		Product	Prob	lem		
Outcomes a	attribut	ted to adv	erse e	event		
death		disal	oility			
	atanina		•	an amalı:		
□ life-thre	_	_ `		anomaly		
hospital	lization	□requ	ired in	tervention		
other:						
Date of eve	ent 05-0	01-00	Date	of report	5/8/2	2000
Describe ev	vent or	problem				
I have only						
everything u					new bedd	ing
and perscrip	tion Li	ndane. No	othing	works!		
Relevant te	ctc/lobe	rotory de	nto.			
Keievani te	515/1ab(natory uz	ııa			
Other rele	vant his	story, incl	luding	g preexisti	ng condit	ion

Triage Unit Sequence #	

Diagnosis for use Lice Event abated after stopped or dose redoesn't apply Lot # Exp. date Event reappeared reintroduction yes Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Diagnosis for use Event reappeared reintroduction yes Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Diagnosis for use Event reappeared reintroduction yes Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address User facility distributor Expiration date If implanted, give serial # If explanted, give	all types of OTC shampoos Pose, frequency, route use reprinted a product of the professional frequency of the professional fr	C. Suspect med	lication(s)				
Dose, frequency, route use typical dosage and frequency	Dose, frequency, route use prical dosage and frequency of to 05-01-00 Diagnosis for use doesn't apply Lot # Exp. date Event reappeared after reintroduction yes Concomitant medical products D. Suspect medical device Grand name Type of device Manufacturer name and address Manufacturer name and address Description of device health professional user facility distributor experial # If implanted, give date erial # If implanted, give date	Name: lindane					
typical dosage and frequency Diagnosis for use Lice Event abated after stopped or dose redoesn't apply Lot # Exp. date Event reappeared reintroduction yes Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Degrator of device	Diagnosis for use Event abated after use stopped or dose reduced doesn't apply	all types	of OTC sha	mpo	oos		
Diagnosis for use Lice Event abated after stopped or dose redoesn't apply Event reappeared reintroduction NDC # Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Derator of device	Diagnosis for use dice Event abated after use stopped or dose reduced doesn't apply Event reappeared after reintroduction yes Concomitant medical products D. Suspect medical device Brand name device Annufacturer name and address Operator of device health professional user facility distributor Expiration date If implanted, give date derice distributed in the profession date distributor distributor Expiration date	Dose, frequency,	route use	The	rapy d	ates	
Diagnosis for use Lice Event abated after stopped or dose redoesn't apply Lot # Exp. date Event reappeared reintroduction yes Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Derator of device	Diagnosis for use since Event abated after use stopped or dose reduced doesn't apply Exp. date Event reappeared after reintroduction yes Concomitant medical products D. Suspect medical device Frand name Expe of device Manufacturer name and address Operator of device health professional user facility distributor Expiration date If implanted, give date atalog # erial #	typical dosage and	l frequency	04-1	12-00	to	
Lice stopped or dose redoesn't apply Lot # Exp. date Event reappeared reintroduction NDC # Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device health profess user facility distributor the standard of the s	stopped or dose reduced doesn't apply Exp. date Event reappeared after reintroduction yes Concomitant medical products Concomitant medical device Grand name Expe of device Manufacturer name and address Operator of device health professional user facility distributor Expiration date If implanted, give date						
Lice stopped or dose redoesn't apply Lot # Exp. date Event reappeared reintroduction NDC # Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Operator of device health profess user facility distributor model # catalog # serial # If implanted, give If explanted,	stopped or dose reduced doesn't apply Exp. date Event reappeared after reintroduction yes Concomitant medical products Concomitant medical device Grand name Expe of device Manufacturer name and address Operator of device health professional user facility distributor Expiration date If implanted, give date	Diagnosis for us	e		Event	abated after use	
Lot # Exp. date Event reappeared reintroduction yes	doesn't apply Event reappeared after reintroduction yes Concomitant medical products D. Suspect medical device Grand name Type of device Manufacturer name and address Operator of device health professional user facility distributor Expiration date findel # atalog # erial # If implanted, give date	_			stoppe	d or dose reduced	
NDC # Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address user facility distributor model #	Pipe of device Manufacturer name and address Manufacturer na				doesn'	t apply	
Preintroduction yes Concomitant medical products D. Suspect medical device Brand name Type of device Manufacturer name and address Derator of device Derator	reintroduction yes Concomitant medical products Concomitant medical products Concomitant medical device Concomitant medical device Concomitant medical device Concomitant medical device Concomitant medical products Concomitant medical device Concomi	Lot#	Exp. date		Event	reappeared after	
D. Suspect medical device Brand name Type of device Manufacturer name and address Description of device	Concomitant medical products D. Suspect medical device Grand name Cype of device Manufacturer name and address Operator of device health professional user facility distributor Expiration date atalog # erial # If implanted, give date				reintro	oduction	
D. Suspect medical device Brand name Type of device Manufacturer name and address Description of device	Concomitant medical products D. Suspect medical device Grand name Cype of device Manufacturer name and address Operator of device health professional user facility distributor Expiration date atalog # erial # If implanted, give date				ves		
D. Suspect medical device Brand name Type of device Manufacturer name and address Derator of device	D. Suspect medical device Grand name Type of device Manufacturer name and address Operator of device health professional user facility distributor Expiration date atalog # erial #		-		<i>J</i>		
Brand name Type of device Manufacturer name and address Departor of device	Annufacturer name and address Operator of device health professional user facility distributor Expiration date atalog # Briand name If implanted, give date	Concomitant me	dical produ	cts			
Brand name Type of device Manufacturer name and address Departor of device	Anufacturer name and address Operator of device health professional user facility distributor Expiration date atalog # Briand name If implanted, give date						
Brand name Type of device Manufacturer name and address Departor of device	Anufacturer name and address Operator of device health professional user facility distributor Expiration date atalog # Briand name If implanted, give date						
Brand name Type of device Manufacturer name and address Departor of device	Anufacturer name and address Operator of device health professional user facility distributor Expiration date atalog # Briand name If implanted, give date						
Type of device Manufacturer name and address Departor of device	Anufacturer name and address Operator of device health professional user facility distributor Expiration date atalog # erial #	D. Suspect medical device					
Manufacturer name and address Operator of device health profess user facility distributor Expiration date model #	Annufacturer name and address Operator of device health professional user facility distributor Expiration date atalog # Briting in the implanted, give date are in the implanted of th	Brand name					
model #	health professional user facility distributor Expiration date atalog # Brian # If implanted, give date	Type of device			_		
model # If implanted, give serial # If explanted, give	user facility distributor Expiration date atalog # Brian # If implanted, give date	Manufacturer na	me and add	lress	Oper	ator of device	
model #	distributor Expiration date atalog # Brian in the distributor If implanted, give date are in the distributor				$\square_{\rm h}$	ealth professional	
model # If implanted, give serial # If explanted, give	Expiration date atalog # If implanted, give date erial #						
model # If implanted, give serial # If explanted, give	nodel # If implanted, give date erial #				\square_{d}	istributor	
catalog # If implanted, give serial # If explanted, give	atalog # If implanted, give date erial #				Expi	ration date	
catalog # If implanted, give serial # If explanted, give	atalog # If implanted, give date erial #	model #					
lot #If explanted, give					If im	planted, give date	
	ot # If explanted, give date						
othor #					_ If exp	planted, give date	
omer #	ther #	other #					
Device available for evaluation?	lovice eveilable for evaluation?		curer / /				
□ yes □ no □ returned to manufacturer//		Concomitant me	dical produ	cts			
□yes □no □returned to manufacturer _/_/ Concomitant medical products	yes no returned to manufacturer//						
☐yes ☐no ☐returned to manufacturer/_/_ Concomitant medical products	yes no returned to manufacturer//	E. Reporter					
Concomitant medical products	yes no returned to manufacturer / / Concomitant medical products	Name and addre	ss	p	hone #	(781)449-6487	
Concomitant medical products E. Reporter	yes no returned to manufacturer / / Concomitant medical products Reporter	The National Pe	diculosis A	ssoc	ciation		
Concomitant medical products E. Reporter Name and address phone # (781)449-6 The National Pediculosis Association	The National Pediculosis Association Teturned to manufacturer _ / _ / Treturned to manufacturer _ / _ / The National Pediculosis Association	P.O. Box 610189	, Newton, N	1A. (02461		
Concomitant medical products E. Reporter Name and address phone # (781)449-6	The National Pediculosis Association Teturned to manufacturer _ / _ / Treturned to manufacturer _ / _ / The National Pediculosis Association		_	oatio	on	Also reported to	
Concomitant medical products E. Reporter Name and address The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461 Health professional Occupation Also repor	In the National Pediculosis Association 2.0. Box 610189, Newton, MA. 02461 Itelalth professional Occupation Also reported to	-					
Concomitant medical products E. Reporter Name and address The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461 Health professional yes Occupation Also reportence of the professional of the professional occupation of the professional occupation of the professional occupation of the professional occupation	The National Pediculosis Association O. Box 610189, Newton, MA. 02461 Lealth professional Occupation Occupation Also reported to manufacturer _/ / / / / / / / / / / / / / / / / / /	-	•	•	an 🔲	distributor	
Device available for evaluation?	ther #	catalog # serial # lot # other # Device available \[\sqrt{yes} \sqrt{\sqrt{no}}\] no	for evaluati	to m	If exp	planted, give date	
			for evaluati	ion?			
		$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to m	anufact	urer//	
I lyas I no I returned to manufacturar / /		Concomitant me	dical produ	cts	ianuraci	urer/_/	
yesnoreturned to manufacturer/_/_ Concomitant medical products	yes no returned to manufacturer/_/	Concomitant inc	uicai produ	CLS			
□yes □no □returned to manufacturer _/_/ Concomitant medical products	yes no returned to manufacturer _/_/	E Paparter					
Concomitant medical products	yes no returned to manufacturer / / Concomitant medical products		ee	n	hone #	(781)///9_6/87	
Concomitant medical products E. Reporter	yes no returned to manufacturer / / Concomitant medical products Reporter			Ĺ		(781)449-6487	
Concomitant medical products E. Reporter Name and address phone # (781)449-6	yes no returned to manufacturer / / Concomitant medical products Reporter Tame and address phone # (781)449-6487						
Concomitant medical products E. Reporter Name and address phone # (781)449-6 The National Pediculosis Association	The National Pediculosis Association						
Concomitant medical products E. Reporter Name and address phone # (781)449-6 The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461	The National Pediculosis Association 2.O. Box 610189, Newton, MA. 02461		_		-		
Concomitant medical products E. Reporter Name and address The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461 Health professional yes Occupation Also report manufac	The National Pediculosis Association O. Box 610189, Newton, MA. 02461 Tealth professional Occupation Occupation Also reported to manufacturer / / / / / / / / / / / / / / / / / /	•	•	•			
Concomitant medical products E. Reporter Name and address The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461 Health professional yes If you do NOT want your identity Value Val	Concomitant medical products E. Reporter Itame and address Che National Pediculosis Association C.O. Box 610189, Newton, MA. 02461 Itealth professional Occupation Yes Ino Tyou do NOT want your identity The National Pediculosis Association Also reported to manufacturer user facility	disclosed to the ma	nufacturer, p	lace	an 🔲	distributor □	

A. Patient Informa				
Patient Identifier		Sex	Weight	
189	06-13-88	female	120	lbs
B. Adverse event				
	Adverse Eve			
Outcomes attribut		event		
death	□disability			
☐ life-threatening	_ ~	•		
hospitalization	•			
other: complain				
Date of event 04-2		e of report	5/5/2	2000
Describe event or complaints of haeda treatment of head lid	iche, fever and e ce (Lindane).	xtreme leth	argy after	
Other relevant his Use of Nix x 3 with	story, including		ng condi	tion

Triage Unit Sequence #	

C. Suspect	medication(s)			
Name: Nix				
linda	ne			
Dose, freque	ncy, route use	The	erapy dates	
			04-03-00	
Lindane x 1	, days	0.0	to 05-05-00	
Diagnosis for	r 11co	<u> </u>	Event abated after us	^
Nix/Lindane a			stopped or dose reduc	
Mix/Lindane a	s directed			
	T		no	
Lot#	Exp. date		Event reappeared afte	er
			reintroduction	
NDC #			yes	
	medical produ	cts		
As described a	above			
D. Suspect i	medical device	е		
Brand name				
Type of device			1	
Manufacture	r name and ado	dress	l —	
			health profession	al
			user facility	
			distributor	
			Expiration date	
madal #				
model #			_	
			If implanted, give da	nte
catalog # serial #			If implanted, give da	nte
catalog # serial # lot #			If implanted, give da	
catalog # serial # lot #			-	
catalog # serial # lot # other # Device availa	ıble f <u>or</u> evaluat		If explanted, give da	
catalog # serial # lot # other # Device availa yes	able for evaluat	to m	If explanted, give da	
catalog # serial # lot # other # Device availa yes	ıble f <u>or</u> evaluat	to m	If explanted, give da	
catalog # serial # lot # other # Device availa yes	able for evaluat	to m	If explanted, give da	
catalog # serial # lot # other # Device availa yes	able for evaluat	to m	If explanted, give da	
catalog # serial # lot # other # Device availayes	able for evaluat no returned medical produ	to m	If explanted, give da	te
catalog # serial # lot # other # Device availa	able for evaluat no returned medical produ	to m	If explanted, give da	te
catalog # serial # lot # Other # Device availayes Concomitant E. Reporter Name and ad The Nationa	able for evaluat no returned medical produ	to m	If explanted, give dananufacturer// hone # (781)449-6487	te
catalog # serial # lot # Other # Device availa	able for evaluation returned medical productions Idress 1 Pediculosis A	passoo	hanufacturer _/_/ whone # (781)449-6487	te
catalog # serial # lot # Other # Device availayes Concomitant E. Reporter Name and ad The Nationa	able for evaluation returned medical productions Idress 1 Pediculosis A	passoo	If explanted, give damanufacturer/_/ hone # (781)449-6487 ciation 02461	te
catalog # serial # lot # Pevice availa yes Concomitant E. Reporter Name and ad The Nationa P.O. Box 610 Health profe yes	able for evaluation returned medical production for the production of the production	p ASSOCIAA. (If explanted, give data nanufacturer/_/ whome # (781)449-6487 ciation 02461 On Also reported	to er

A. Patient Inform			
Patient Identifier		Sex	Weight
188	01-08-1989	female	89 lbs
B. Adverse event			
	e Event & Prod		em
Outcomes attribut	_	event	
death	disability		
☐ life-threatening			
hospitalization	☐ required in	ntervention	
other: hair loss			
Date of event 02/2	20/00 Date	e of report	5/2/2000
Describe event or	problem		
for the last 2 years r	ny chrildren hav	ve been inf	ested with
head lice. i have used everytin	ng over the coun	ter and eve	erv
product,rx,and hom			лу
	•	•	
Relevant tests/labo	oratory data		
Other relevant his	story, including	g preexisti	ng condition

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name: lindane				
i have us	sed almost ev	ery	product	on this list
Dose, frequency	, route use	The	rapy d	ates
every 7 days		08/9	9	to
				05/00
Diagnosis for us	se		Event	abated after use
head lice infestion	1		stoppe	d or dose reduced
			yes	
Lot#	Exp. date		Event	reappeared after
				duction
			yes	
NDC# -	-		<i>j</i> 03	
Concomitant me	=			
as i have stated i			to the li	ce i still remove
manualy live lice	and nits daily	y		
D. Suspect med	dical davice			
D. Suspect med Brand name	uicai device	,		
Type of device				
Manufacturer n	ame and add	lress	Oper	ator of device
			l Â	ealth professional
				ser facility
			\square_{d}	istributor
				ration date
model #			_ 🖳	
catalog #			If im	planted, give date
serial #			-	
lot # other #			If exp	planted, give date
	C14	9		
Device available $\square_{ m yes} \ \square_{ m no}$	returned			urer / /
Concomitant me			arrarae	
	_			
E. Reporter				
Name and addre	ACC.	n	hone #	(781)449-6487
The National Pe		드		(101)117-0101
P.O. Box 610189				
Health profession	·			Also reported to
\mathbf{V}_{yes}		jat10	711	Also reported to manufacturer
If you do NOT wa		tv		user facility
disclosed to the ma	•	•	an 🔲	distributor

	-		
A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
158	18/05/83	female	130 lbs
B. Adverse even	t or product p	roblem	
	Product Prob	lem	
Outcomes attribu	ted to adverse e	event	
□ _{death}	disability		
☐ life-threatening		anomaly	
hospitalization		ntervention	
other:	— required in	iter vention	
Date of event 04/0	00/ Date	of report	4/19/2000
Describe event or	=		
Two treatments wit			•
containing Malathio			
discovered after 6 d	•	er II days.	3rd
application being tr	ieu.		
Relevant tests/lab	oratory data		
	•		
			74.4
Other relevant his	story, including	g preexisti	ng condition

Triage Unit Sequence #	

C. Suspect me	edication(s)			
Name: malathi	on			
Dose, frequency	y, route use	The	rapy d	ates
liberal application		2/04		
and hair				to 19/04/00
Diagnosis for u	Se	<u> </u>	Event	abated after use
visible lice and n				d or dose reduced
visible lice and li	its			
 Lot #	E . 1.4.		no	
Lot #	Exp. date			reappeared after
]	reintro	duction
NDC# -			yes	
Concomitant m	edical produ	rts		
none	carcar produ	- 113		
none				
D. Suspect me	dical device	è		
Brand name				
Type of device				
Manufacturer r	name and add	lress	Oper	ator of device
			\square_{h}	ealth professional
				ser facility
			\sqcup_{d}	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial # lot #			TC	.14.3
other #			ın exp	planted, give date
Device available	a for avaluat	ion?		
	returned		anufact	curer / /
Concomitant m				
E. Reporter				
Name and addr	ogg	nl	none #	(781)449-6487
- 100		드		(781)449-0487
The National P				
P.O. Box 61018				
Health professi ✓ yes □ r		patio	n	Also reported to
·				manufacturer user facility
If you do NOT w disclosed to the n	•	•	an 🔲	distributor

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
157	01/15/1962	female	135	lbs
B. Adverse event	or product p	roblem		
Advers	e Event & Prod	luct Proble	em	
Outcomes attribut	ted to adverse o	event		
\Box_{death}	disability			
☐ life-threatening	□ congenital	anomaly		
$\square_{ m hospitalization}$	required in	ntervention		
other: keeps con	mming back			
Date of event 04/2	28/2000 Date	e of report	4/29/20	000
Describe event or	problem			
this has been an on				
have been using (alp	oharma) as a sha	mpoo.and a	a flea comb).
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng conditi	ion

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: lindane					
kwell					
Dose, frequency, route use Th			rapy d	ates	
shampo 3 times a month 199		199	7	4	
and about 9 mo a year				to 2000	
Diagnosis for us	<u> </u>		Event	abated after use	
head lice			stopped or dose reduce		
nead nec					
T 4 11	D 14		no		
Lot#	Exp. date			reappeared after	
			reintroduction		
NDC# -			yes		
Concomitant me	-				
Rid to spray the h	ouse for 3 ye	ears 7	7/1/97to	4/29/2000	
D. Suspect med	dical device)			
Brand name					
Type of device			T _a		
Manufacturer na	ime and add	lress		ator of device	
				ealth professional	
				ser facility	
				istributor	
			Expi	ration date	
model #					
catalog #			- III im	planted, give date	
serial #					
lot # other #			- If exp	olanted, give date	
Device available □ _{yes} □ _{no}	returned	to m	anufact	urer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	ss	р	hone #	(781)449-6487	
The National Pe	diculosis A	ᆫ		·	
P.O. Box 610189	, Newton, M	1A. (02461		
Health professio	nal Occuj	patio	n	Also reported to	
$ \mathbf{v}_{\text{yes}} $	1 -			manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma			an 🔲	distributor	

A. Patient Inform	ation		
Patient Identifier	Date of birth	Sex	Weight
154	11/26/2000	male	49 lbs
B. Adverse event	or product p	roblem	
Advers	e Event & Prod	luct Proble	em
Outcomes attribut	ted to adverse e	event	
\Box_{death}	disability		
☐ life-threatening		anomaly	
hospitalization		ntervention	
other: Flu sym		iter vention	
			1/22/2000
Date of event 4/16		of report	4/22/2000
Describe event or			
Treated with NIX C			
Morning of April 16	-		_
started and lasted up			
tonsils, he could had bad ear infection.	rdiy swanow an	a enaea up	willi a very
bad ear infection.			
Dolovont tosts/lobe	matamy data		
Relevant tests/labo	oratory data		
Other relevant his	story, including	g preexisti	ng condition
My son had head lie			_
treatment he had the	-	-	

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: Nix					
Dose, frequency, route use The			apy d	ates	
One application, l	eft on for	4/14/	00		
ten minutes.				to 4/14/00	
Diagnosis for us	e	I	Event	abated after use	
l appl. left on for		s	toppe	d or dose reduced	
			doesn'	t apply	
Lot #	Exp. date	I	Event	reappeared after	
		r	reintroduction		
			doesn'	t apply	
NDC# -	-			L. LA	
Concomitant me	dical produ	cts			
				ng with Olive Oil	
left on for three ho				head with	
shower cap or pla	stic. April 22	2,200	0.		
D. Suspect med	lical device	•			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			\square_{h}	ealth professional	
			user facility		
			distributor		
				ration date	
model #			Z.ipii	auton dute	
catalog #			If im	planted, give date	
serial #			1	, ,	
lot #			If ext	planted, give date	
other #					
Device available	for evaluati	ion?	1		
$\square_{\text{yes}} \square_{\text{no}}$	_		ınufact	urer/_ /	
Concomitant me					
	•				
E. Reporter					
Name and address phone # (781)449-6487					
The National Pe	diculosis A	ssoci	iation		
P.O. Box 610189, Newton, MA. 02461					
Health professio	1 -	oation	1	Also reported to	
yes no manufacturer					
If you do NOT want your identity user facility					
disclosed to the ma	nufacturer, p	lace a	ın 🔲	□distributor	

A. Patient Inform				
Patient Identifier		Sex	Weight	
152	2-7-98	female	24	lbs
B. Adverse event				
	e Event & Pro		em	
Outcomes attribut		event		
□ death	□disability			
☐ life-threatening		-		
hospitalization		ntervention		
other: reoccurin	ng lice; 5 times	now in just	a couple of	f m
Date of event 4/16	5/00 Dat	e of report	4/17/2	000
had head lice 5 time and 4 NIX treatmen furniture, hair cuts a	ats, professiona	lly cleaned	carpet,	
Other relevant his Alex(2) has Cornelia treated for the lice a showed any signs of sleeplessness and av occurrence) Jacquier	story, including a De Lange Synull five times wist adverse reactivaking as if in p	drome. She th NIX or I on,except fo	e has been Rid and has or	sn't

Triage Unit Sequence #	

C. Suspect me	dication(s)				
Name: Nix					
Dose, frequency	, route use	The	rapy d	ates	
5 times on all 3 p	eople over	2/20		to	
the past 2 month	S			to 4/15	
Diagnosis for us	se]	Event abated after use		
head lice		:	stoppe	d or dose reduced	
			doesn't apply		
Lot#	Exp. date		Event	reappeared after	
]	reintroduction		
			yes		
NDC# -	-		J		
Concomitant me	edical produ	cts			
Rid was used firs				-	
recommendation	of a physicia	n for	the oth	ner 4 treatments	
D. Suspect me	dical device)			
Brand name					
Type of device					
Manufacturer n	ame and add	lress	Oper	ator of device	
				ealth professional	
			user facility distributor		
3.1//			Expii	ration date	
model # catalog #			If im	planted, give date	
cataiog			· [· · · · · · · · · · · · · · · · · ·	pranticu, grve unic	
lot #			If over	alantad giva data	
other #			ın exp	planted, give date	
Device available	for evaluati	ior?	1		
$\square_{\text{yes}} \square_{\text{no}}$			anufact	urer / /	
			anuraci		
Concomitant medical products					
E. Reporter					
Name and addre	ess	pl	hone #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to					
$\mathbf{v}_{\mathrm{yes}}$ $\mathbf{v}_{\mathrm{new}}$				manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the manufacturer, place an distributor				distributor	

A Bationt Info	rm.	etion				
A. Patient Info				~		
Patient Identif			irth	Sex	Weight	-,
151		19/87/		female	41	lbs
B. Adverse ev	ent					
		Product	Prob	lem		
Outcomes attri	ibut	ted to adv	erse e	event		
☐ death		∐disal	oility			
☐ life-threaten	iing	\Box_{cong}	enital	anomaly		
$\square_{\text{hospitalizat}}$	ion	\square_{requ}	ired in	ntervention		
other:						
Date of event	20/0	00/	Date	of report	4/14/2	2000
Describe event						
Product failure	01	problem				
Relevant tests/l	lahe	ratory da	ata			
		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				
Other relevant	his	story, incl	luding	g preexisti	ng condi	tion

Triage Unit Sequence #	

C. Cuanast mas	liantinu(a)				
C. Suspect med					
Name: malathion					
Hair lice shampoo; permethrin, piperonyl, excipients					
Dose, frequency, route use The			rapy d	ates	
Shampoo 300ml		15/0)2	to	
Malathion (0.5% 1	malathion)			13/04	
Diagnosis for us	e		Event	abated after use	
Head Lice			stoppe	d or dose reduced	
			doesn'	t apply	
Lot#	Exp. date		Event	reappeared after	
			reintroduction		
			doesn'	t apply	
NDC# -	-			· ··L.E.2	
Concomitant me	dical produ	cts			
D. Suspect med	lical device				
Brand name	Modified VICC				
Type of device					
				.4£ J	
Manufacturer na	ame and add	iress		ator of device	
			$\square_{\rm h}$	ealth professional	
			$ \square_{\mathrm{u}}$	ser facility	
				istributor	
			Expii	ration date	
model #			If im	planted, give date	
catalog #			. 11 1111 _]	pianteu, give date	
serial #			-		
lot #			- If exp	olanted, give date	
other #					
Device available □ _{yes} □ _{no}			anufact	urer / /	
Concomitant me	dical produ	cts			
	-				
E. Reporter					
Name and addre	ss	p	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	ciation		
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occup	oatio	n	Also reported to	
$ \mathbf{V}_{\text{yes}} \square_{\text{no}} $	_		-	manufacturer	
If you do NOT want your identity user facility					
				distributor	
disclosed to the ma	muracturer, p	тасе	an 🔳	- uisii10ut01	

A Bationt Inform			
A. Patient Inform			
Patient Identifier		Sex	Weight
149	11/19/92	female	58 lbs
B. Adverse event			
	Product Prob		
Outcomes attribut	ted to adverse o	event	
□death	□disability		
☐ life-threatening	Congenital	anomaly	
hospitalization	☐required in	ntervention	
other:			
Date of event 3/00) Date	of report	4/11/2000
Describe event or	problem		
We used Nix twice,	mayonaise treat	ment once,	and Lindane,
and still did not get	rid of the lice.		
Relevant tests/labo	oratory data		
	•		
Other relevant his	story, including	g preexisti	ng condition
	• ,		J

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Nix					
lindane,	and mayonai	se			
Dose, frequency, route use Therapy dates					
Nix two times, ma	ayonaise	3/10			
once, Lindane onc	-			to 4/10	
Diagnosis for us	<u></u> е	l	Event	abated after use	
did not kill lice	-			d or dose reduced	
aid not kin nee				t apply	
Lot#	Exp. date			reappeared after	
	-			duction	
			doesn't apply		
NDC# -	-		uoesn	і арріу	
Concomitant me	dical produ	cts			
D. Suspect med	dical device)			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
				ealth professional	
			user facility distributor		
			□a	istributor	
			Expi	ration date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	planted, give date	
other #					
Device available					
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	□ _{returned}	to ma	nufact	urer/_/	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	SS	ph	one #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occup	oatio	n	Also reported to	
$\mathbf{\nabla}_{\mathrm{yes}}$ $\mathbf{\square}_{\mathrm{no}}$				manufacturer	
If you do NOT was	nt vour identi	itv		user facility	
disclosed to the ma			ın 🔳	distributor	
	p				

A. Patient Inform	ation					
Patient Identifier	Date of b	irth	Sex	Weight		
147	09-23-91		female	50	lbs	
B. Adverse even	t or produ	uct pr	oblem			
	Product	Prob	lem			
Outcomes attribu	ted to adv	erse e	event			
death	\Box disab	oility				
☐ life-threatening	\Box_{cong}	enital	anomaly			
hospitalization	□requ	ired in	tervention			
other:						
Date of event 04-	04-00	Date	of report	4/7/2	2000	
Describe event or	problem		-			
product failure						
Relevant tests/laboratory data						
Other relevant his	story, incl	luding	g preexisti	ng condi	tion	

Triage Unit Sequence #	

C Suppost mas	diantian(a)				
C. Suspect med	lication(s)				
Name: lindane					
nix					
Dose, frequency,	, route use	The	rapy d	ates	
once every two w	eeks	03-0	0		
				to 04-05-00	
Diagnosis for us	P	<u> </u>	Event	abated after use	
headlice				d or dose reduced	
neadifice					
			no		
Lot #	Exp. date]	Event	reappeared after	
]	reintro	duction	
NID C II		_	yes		
NDC# -	-				
Concomitant me	dical produ	cts			
D. Suspect med	dical device	•			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
			_	ealth professional	
				ser facility	
				istributor	
				ration date	
model #			LAPI	auton dute	
model # catalog #			If im	planted, give date	
serial #			·	, ,	
lot #			If ext	planted, give date	
other #				granica, granica	
Device available	for evaluati	ion?			
			anufact	urer / /	
Concomitant me	dical produ	cts			
	-				
E. Reporter					
Name and addre	SS	pl	hone #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189	P.O. Box 610189, Newton, MA. 02461				
I .	, ,				
Health professio		patio	n	Also reported to	
Health professio ✓ yes □no	nal Occuj	patio	n	Also reported to manufacturer	
	nal Occuj		n		

A. Patient	Inform	otion				
			41	G	*** * 1 4	
Patient Ide			rth	Sex	Weight	11
5 4 1	146	01/24/96		male	48	lbs
B. Advers	e even					
		Adverse				
Outcomes	attribut			event		
death		∐disabi	•			
☑ life-thre				anomaly		
hospita	lization	∠ requir	ed in	tervention		
other:						
Date of eve	ent 01/2	24/96	Date	of report	4/5/2	2000
Describe e	vent or	problem				
born with b	_	-	_	-		
right lung. s					-	sed
with strabis further cros			ective	e lenses to	prevent	
ruruici cros	sing or o	cycs.				
Relevant te	ests/laho	ratory dat	9			
Keie vant te	.5 t5/1ab(natory dat	a			
Other		4 !				L ²
Other rele	vant his	story, inclu	ding	g preexisti	ng condit	lion

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: lindane				
Dose, frequency,	route use	The	rapy d	ates
once	Toute use	199		accs
once		199	3	to
			1	1995
Diagnosis for use	e			abated after use
mother had genital	lice while		stoppe	d or dose reduced
pregnant with alec	;		no	
Lot#	Exp. date		Event	reappeared after
	-			duction
NDC# -	-		doesn'	t apply
Concomitant me	dical produ	cts		
D. Suspect med	lical device			
	iicai device			
Brand name Type of device				
Manufacturer na	me and ade	Irocc	Oper	ator of device
Manufacturer na	illic allu auc	11 688	I —	
				ealth professional ser facility
				istributor
			Expii	ration date
model #			- If im	planted, give date
catalog #			- 11 1111	pianteu, give uate
serial # lot #			TC	.14.1
other #			- III exp	planted, give date
	e 1 4			
Device available $\square_{\text{yes}} \square_{\text{no}}$				
Concomitant med	dical produ	cts	ianunaci	urer//
Concomitant medical products				
E. Reporter				
Name and address phone # (781)449-6487				
The National Pediculosis Association				
P.O. Box 610189	, Newton, M	1A. (02461	
Health profession	nal Occuj	patio	n	Also reported to
$ \mathbf{V}_{\text{yes}} \square_{\text{no}} $,			manufacturer
If you do NOT war	nt your ident	ity		user facility
disclosed to the ma			an 🔳	□distributor

A. Patient Inform	ation						
Patient Identifier	Date of b	irth	Sex	Weight			
142	08-16-19	992	female	48	lbs		
B. Adverse event	or prod	uct pi	roblem				
	Product	Prob	lem				
Outcomes attribut	ed to adv	erse e	event				
death	disal	oility					
life-threatening	\Box_{cong}	enital	anomaly				
hospitalization	□requ	ired in	ntervention				
other:							
Date of event 03-	15-00	Date	of report	4/2/2	2000		
Describe event or	problem	•					
Kids got it. Treated				Vacuum	ed,		
sprayed, bagged toy	ys, etc., w	on't go	o away.				
Relevant tests/laboratory data							
Other relevant his	Other relevant history, including preexisting condition						
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		5 Preemser	ng condi			

Triage Unit Sequence #	

C Suspect mod	lication(s)			
C. Suspect med	ilcation(s)			
Name: lindane				
Nix				
Dose, frequency	, route use	The	rapy d	ates
1 bottle Nix		3-15	5-00	to
3 x wk				4-1-00
Diagnosis for us	e			abated after use
no instructions			stoppe	d or dose reduced
			no	
Lot#	Exp. date		Event	reappeared after
				duction
NDC# -	-		yes	
Concomitant me	dical produ	cts		
Lindane - eight m	onths ago, Ni	x se	veral tin	nes
D. Suspect med	dical device	•		
Brand name				
Type of device				
Manufacturer na	ame and add	lress	Oper	ator of device
		00.		ealth professional
				ser facility
				istributor
			Expii	ration date
model #			- If im	planted, give date
catalog #			- 11 1111	pianieu, give uate
serial # lot #			TC	.14.1
other #			- In ext	planted, give date
	C			
Device available $\square_{ m yes} \ \square_{ m no}$				urer / /
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	ss	p	hone #	(781)449-6487
The National Pediculosis Association				
P.O. Box 610189, Newton, MA. 02461				
Health professio	nal Occup	patio	n	Also reported to
	_			manufacturer
If you do NOT wa	nt your identi	ity		user facility
disclosed to the ma			an 🔲	distributor

A. Patient Inform	ation					
Patient Identifier	Date of bi	rth	Sex	Weight		
141	02/13/89		female	89	lbs	
B. Adverse event	or produ	ct pi	roblem			
	Product	Prob	lem			
Outcomes attribut	ed to adve	erse e	event			
death	disab	ility				
☐ life-threatening	\Box_{conge}	enital	anomaly			
hospitalization	□ requi	red in	ntervention			
other:						
Date of event 02/0	01/2000	Date	of report	4/1/2	2000	
Describe event or	problem					
We have tried since				g is worki	ng	
we have spent abou	t 700 dolla	rs we	have had			
Relevant tests/laboratory data						
04 1 43		1.	• .•		4.	
Other relevant his	story, inclu	ıdınş	g preexisti	ng condi	tion	
none						

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: Nix					
Rid, kwe	ll, Nemph oi	1			
Dose, frequency,	, route use	The	rapy d	ates	
one bottle family	size per	12/0)1/99		
person	-			to 04/01/2000	
Diagnosis for us	<u> </u>		Event :	abated after use	
HEAD LICE	-		stopped or dose reduce		
HEAD LICE					
	- .		no		
Lot #	Exp. date			reappeared after	
			reintro	duction	
NIDC #			doesn'	t apply	
NDC# -	-				
Concomitant me	dical produ	cts			
D. Suspect med	dical device)			
Brand name					
Type of device					
Manufacturer na	me and add	lress	1 —	ator of device	
			□h	ealth professional	
				ser facility	
			Шd	istributor	
			Expir	ation date	
model #					
catalog #			- If im]	planted, give date	
serial #					
lot # other #			_ IIf exp	olanted, give date	
Device available $\square_{\text{yes}} \square_{\text{no}}$				urer//	
Concomitant me					
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occuj	patio	n	Also reported to	
$\mathbf{v}_{\mathrm{yes}} \square_{\mathrm{no}}$)			manufacturer	
If you do NOT was	nt your identi	ity	_	user facility	
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor	

A. Patient Inform	ation							
Patient Identifier	Date of birt	h Sex		Weight				
138	7-3-1991	female	e	75	lbs			
B. Adverse even	t or product	problen	1					
	Product Pr	oblem						
Outcomes attribut	ted to advers	e event						
\Box_{death}	death disability							
☐ life-threatening	☐ life-threatening ☐ congenital anomaly							
hospitalization	required	l interven	tion					
other:								
Date of event 3-2	3-2000 D	ate of rep	ort	3/30/	2000			
Describe event or	problem							
after treating with n	_							
a couple of days and lice. and still numor		_						
nits very well. is the					uie			
		,	5					
Relevant tests/labo	oratory data							
Other relevant his	story, includ	ing preex	cisti	ng cond	ition			
-								

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name: Nix				
Dose, frequency	route use	The	erapy d	ates
				ates
used twice within period,	a four day	3-23	3-2000	to 3-29-2000
Diagnosis for us	e			abated after use
found head lice ar	nd nits in chil	ds	stoppe	d or dose reduced
hair,			doesn'	t apply
Lot#	Exp. date		Event	reappeared after
			reintro	oduction
NDC# -	<u> </u>		doesn'	t apply
Concomitant me	dical produ	cts		
D. Suspect med	dical device)		
Brand name				
Type of device				
Manufacturer na	ame and add	iress	1 —	ator of device
			l H	ealth professional
			□u	ser facility
			-	istributor
"			Expi	ration date
model # catalog #			- If im	planted, give date
serial #			- ,	g
lot #			If exp	olanted, give date
other #				<u>-</u>
Device available				, ,
yes no Concomitant me			nanufact	urer/_/
concomitant me	dicai produ	cus		
E. Reporter				
Name and addre	SS	p	hone #	(781)449-6487
The National Pe	diculosis A	sso	ciation	
P.O. Box 610189	Newton, N	ΙΑ . (02461	
Health professio ✓ yes □no		atio	on	Also reported to manufacturer
If you do NOT wa		itv		user facility
disclosed to the ma	•	•	an 🔲	distributor

A. Patient Inform	ation						
Patient Identifier	Date of birth	Sex	Weight				
135	05/24/71	female	128	lbs			
B. Adverse event	or product p	roblem					
	Adverse Ev	ent					
Outcomes attribut	ted to adverse o	event					
death	disability						
☐ life-threatening	□ congenital	anomaly					
hospitalization	required in	ntervention					
other: prematur	e labor and diag	gnsed with	cyst on br	ain			
Date of event 7/95	Date	e of report	3/29/2	2000			
Describe event or	problem						
had genital lice, give	en lindane sham	poo by e.r.	doctor				
Relevant tests/labo	Relevant tests/laboratory data						
Other relevant his		g preexisti	ng condi	tion			
app.3 months/4 mo	nths pregnant						

Triage Unit Sequence #	

C. Suspect med	lication(s)			
Name: lindane				
came wit	no label			
Dose, frequency,	route use	Ther	apy d	ates
ised once		7/95		
				to 7/95
Diagnosis for us	e	l F	Event	abated after use
genital lice		s	toppe	d or dose reduced
,e			yes	
Lot #	Exp. date	—		
Lot #	Ехр. чан			reappeared after
		r	emtro	oduction
NDC# -	-		no	
Concomitant me	dical produ	 cts		
none	1	-		
D. Suspect med	lical device	•		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
			l □h	ealth professional
			l III u	ser facility
			-	istributor
			Expi	ration date
nodel #			If im	planted, give date
catalog # serial #			11 1111	pianieu, give uate
ot #			If evi	olanted, give date
other #			II CA	Jameed, give date
Device available	for evaluati	ion?		
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			nufact	turer//
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	22	nh	one #	(781)449-6487
The National Pe				(,01)117 0107
P.O. Box 610189				
				Also way and all 4
Health profession yes no		patior	ı	Also reported to manufacturer
f you do NOT was		its		user facility
lisclosed to the ma	-	-	n 🔲	distributor

A. Patient Inform	otion							
		~						
Patient Identifier		Sex	Weight					
131	8/22/75	male	185 lbs					
B. Adverse event	Product Prob							
O								
Outcomes attribut		event						
☐ death	☐ disability	1						
I —	☐ life-threatening ☐ congenital anomaly							
hospitalization	☐ required in	itervention						
other:								
Date of event 06/2		of report	3/21/2000					
Describe event or								
both lindane, used		-						
episodes, and elimit								
erradicate scabies, a product was used co								
product was used co	offectiy-suspect	resistant s	lables					
Relevant tests/labo	ratory data							
	zauory amon							
Other relevant his	story, including	g preexisti	ng condition					

Triage Unit Sequence #	

C. Suspect	medicati	on(s)				
Name: linda	ane					
elim	ite					
Dose, freque	ency, rout	e use	The	rapy d	ates	
one treatment	t followed	by	6/99)		
another 7 day		,			to 2/00	
Diagnosis fo	r use			Event	abated after use	
scabies	- 450				d or dose reduced	
scaules						
"				no		
Lot #	Exp.	date			reappeared after	
				reintro	oduction	
NDC #	I	_		yes		
Concomitant	t medical	nrodu	ets			
eucalyptus oi		_	· us			
eucaryptus of	ı/ tea tree ()II				
D. Suspect	medical	device				
Brand name						
Type of device						
Manufacture		nd add	lress	Oper	ator of device	
	health professional					
				\square_{u}	ser facility	
					istributor	
				Expir	ration date	
model #						
catalog #				If im	planted, give date	
serial #						
lot #				If exp	planted, give date	
other #						
Device availa				anufact	urer _ /_ /	
Concomitant	t medical	produ	cts			
E. Reporter						
Name and address phone # (781)449-6487						
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
Health professional Occupation Also reported t					Also reported to	
✓ yes □no □ manufacturer □ user facility						
If you do NOT	•		•	I	distributor	
disclosed to th	ie manutac	turer, p	ıace	an 🔳		

A. Detient	loof a more	-1:				
A. Patient				a	***	
Patient Ide		Date of bir	th	Sex	Weight	
_	130	04/22/95		female	42	lbs
B. Adverse	e event	t or produc				
		Product P				
_	attribut	ted to adver		vent		
death		∐disabili	ity			
☐ life-thre	atening	\Box_{congen}	ital a	anomaly		
$\square_{\mathrm{hospital}}$	lization	require	d in	tervention		
other:						
Date of eve	ent 03/1	13/00 D	ate	of report	3/20/2	000
Describe ev	vent or	problem				
		MONDAY I				
		WICE ON W				
		HT SOME				
TREATED	HEK W	ITH THAT	. 51	ILL FOUI	NDLIVE	
LICL						
Relevant te	sts/labo	oratory data	1			
Other relev	vant his	story, includ	ling	preexisti	ng condit	ion

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: Nix					
kwell, R	ID				
Dose, frequency,	route use	The	rapy d	ates	
1X MON,2 X TU	ES, 2X	03/1	3/00	to	
WED 1X SUN				to 03/19/00	
Diagnosis for us	e		Event abated after use		
ITCHING, RED I	NECK,		stoppe	d or dose reduced	
WHITE EGGS IN	HAIR		doesn'	t apply	
Lot#	Exp. date		Event	reappeared after	
			reintro	duction	
NDC# -	_		doesn'	t apply	
Concomitant me	dical produ	cts			
I THINK SHE HA	=		Y OF F	EXPOSURE	
	10 11110 1 2		. 0	05 CTL	
D. Suspect med	lical device	;			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			\square_{h}	ealth professional	
			user facility		
			distributor		
			Expi	ation date	
model #			_		
catalog #			If im	planted, give date	
serial #					
lot #			If exp	olanted, give date	
other #					
Device available $\square_{\mathrm{yes}} \ \square_{\mathrm{no}}$			anufact	urer / /	
Concomitant me					
E. Reporter					
Name and addre	Name and address phone # (781)449-6487				
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
	Health professional Occupation Also reported to				
C 11.					
-	If you do NOT want your identity				
disclosed to the ma	ınufacturer, p	lace	an 🔲	□distributor	

21200211					
A. Patient Inform					
Patient Identifier	Date of bi	rth	Sex	Weight	
125	10-23-62		female	140	lbs
B. Adverse event	or produ	ct pı	oblem		
Advers	e Event &	Prod	uct Proble	em	
Outcomes attribut			event		
death	✓ disabi	lity			
☐ life-threatening	\Box_{conge}	nital	anomaly		
hospitalization	requir	ed in	tervention		
other: SIDE EF	FECTS				
Date of event 02-	14-00	Date	of report	3/15/	2000
Describe event or			<u> </u>		
BROKE OUT ON I	_	RMS	SHOULD	ERS,&	
BELTLINE, JUST	AFTER M	Y 7	YR OLD D	AUGHT	`ER
CONTRACTED &	I DID HE	R TF	REATMEN	T FOR	
HEAD LICE USIN	G RID				
D. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.					
Relevant tests/labo	oratory dat	a			
Other relevant his	story, inclu	ding	g preexisti	ng condi	tion
PSORISIS, SINCE	THE AGE	OF 2	20, NOW A	PPEARS	3
TO BE CLEARING					
TRIAMCINOLON					
HOWEVER,STILL	DON'T SE	EEM	100% CUI	RED	

C. Suspect medication(s)							
Name: lindane							
.1%, LOTION & SHAMPOO							
Dose, frequency, route use The			rapy d	ates			
			14-00	t o			
REPEATED SAN				to 3-14-00			
DAVE FOLLOW Diagnosis for us			Event	abated after use			
SCABIES			stoppe	d or dose reduced			
			no				
 Lot #	Exp. date			7.0			
Lot #	Ехр. чан			reappeared after			
			reintro	oduction			
NDC# -	-		yes				
Concomitant me	dical produ	cts	1				
TRIAMCINOLO	=						
.1% CREAM							
D. Suspect med	lical device	,					
Brand name							
Type of device							
Manufacturer na	me and add	lress	s Oper	ator of device			
health professional							
user facility							
			distributor				
			_	ration date			
model#			Expii	ation date			
model # catalog #			If implanted, give date				
serial #							
lot #			If exp	planted, give date			
other #							
Device available $\square_{yes} \square_{no}$				turer / /			
Concomitant me							
E. Reporter							
Name and address phone # (781)449-6487							
The National Pediculosis Association							
P.O. Box 610189, Newton, MA. 02461							
Health professional Occupation Also reported							
$ \mathbf{V}_{\text{yes}} $	· I 🗆						
If you do NOT want your identity user facility							
disclosed to the manufacturer, place an distributor							

A. Patient Inform	ation						
Patient Identifier	Date of bi	irth	Sex	Weight			
116	02/05/97		female	38	lbs		
B. Adverse event	or produ	ict pi	roblem				
	Product	Prob	lem				
Outcomes attribut	_		event				
death	∐disab	•					
☐ life-threatening	□conge	enital	anomaly				
hospitalization	□requi	red ir	ntervention				
other:							
Date of event 8/99	9-3/00	Date	of report	3/7/2	2000		
Describe event or	problem						
Resistace to Rid, Ni	x, Kwell, a	and S	cabie presc	ription			
Relevant tests/laboratory data							
Other relevant his	story, incl	uding	g preexisti	ng condi	tion		

Triage Unit Sequence #	

C. Suspect med	lication(s)					
Name: Rid	· · ·					
Nix						
Dose, frequency,	route use	The	nerapy dates			
Rid & Kwell once		8/99				
prescription three		0/))		to 3/00		
		-	F4			
Diagnosis for us	e		Event abated after use			
didn't work		2	stopped or dose reduce			
			no			
Lot #	Exp. date	j	Event 1	reappeared after		
]	reintro	duction		
			doesn'	t apply		
NDC# -	-		uocsii	с ирргу		
Concomitant me	dical produ	cts				
D. Suspect med	lical device	,				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
			\square_{h}	ealth professional		
			user facility			
				istributor		
			Expir	ation date		
model #			2			
catalog #			If im	planted, give date		
serial #				. , ,		
lot #			If ext	planted, give date		
other #				, g		
Device available	for evaluati	ion?	ı			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			anufact	urer//		
Concomitant me	dical produ	cts				
E. Reporter						
	99	n l	#	(791)///0 6/197		
Name and address phone # (781)449-6487 The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
Health professional Occupation Also reported to						
$\mathbf{\nabla}_{\text{yes}} \mathbf{\square}_{\text{no}}$	-	Jacio	••	manufacturer		
If you do NOT was		its		user facility		
disclosed to the ma	-	-	an 🔳	distributor		

A Buthauti								
A. Patient I								
Patient Ider	ıtifier	Date of b	irth	Sex	Weight			
	114	11-24-85	5	female	125	lbs		
B. Adverse	event	or prod	uct pi	roblem				
		Product	Prob	lem				
Outcomes a	ttribut	ted to adv	erse e	event				
\Box_{death}		\Box_{disal}	bility					
□ _{life-threa}	□ life-threatening □ congenital anomaly							
$\square_{ m hospitali}$	zation	\square_{requ}	ired in	ntervention				
other:								
Date of ever	nt 08-0	06-99	Date	of report	3/3/2	2000		
Describe eve			Duit	orreport	3/3/2	2000		
No products		_	ice in	mv hair i've	e tried Lad	line		
about 3 times		_		-				
Relevant tes	ts/labo	oratory da	ata					
Other releva	ant his	story, inc	luding	g preexisti	ng condit	tion		
		- '		_	_			

Triage Unit Sequence #	

-				
C. Suspect m	edication(s)			
Name: Kwell				
Dose, frequen	cy, route use	The	rapy d	ates
3 times	• /		6-99	
		000	0 ,,	to 01-01-00
Diagnosis for	1160	<u> </u>	Event	abated after use
Ü	use			d or dose reduced
Lice		ľ		
			doesn	t apply
Lot #	Exp. date			reappeared after
]	reintro	oduction
NDC //			doesn	't apply
NDC# -	-	ᆜ		
Concomitant r	nedical produ	cts		
D. Suspect m	edical device)		
Brand name				
Type of device			T ₀	
Manufacturer	name and add	iress	آ ا	ator of device
				ealth professional
				ser facility istributor
			_	
			Expi	ration date
model #			If im	planted, give date
catalog # serial #			ļ.,	pianicu, give uaic
lot #			If ex	olanted, give date
other #			III CA	Janteu, give date
Device availab	le for evaluat	ion?		
	returned		anufact	turer / /
Concomitant r				
C Depositor				
E. Reporter				(701) 440 6407
Name and add		드		(781)449-6487
The National	Pediculosis A	ssoc	iation	
P.O. Box 6101	89, Newton, N	1A . 0	2461	
Health profess		patio	n	Also reported to
∠ yes □	l _{no}			manufacturer
If you do NOT	-	-		user facility
disclosed to the	manufacturer, p	lace a	an 🔳	□distributor

•			
A. Patient Inform			
Patient Identifier	Date of birth	Sex	Weight
111	03/13/89	female	82 lbs
B. Adverse event	or product p	roblem	
	Product Prob	lem	
Outcomes attribut death life-threatening hospitalization	disability	anomaly	ı
other:			
Date of event 02/2	26/00 Date	e of report	3/1/2000
Describe event or Nix and Lindane fai remove nits but have only small amounts to find any after suc you can	led to kill lice.We had trouble fin of lice on our death agressive treath	ding lice. Vaughter bu	We have seen t are dismayed
Relevant tests/labo		g preexist	ing condition

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: lindane					
Dose, frequency, route use Therapy dates					
One bottle???once	;	02/2	27/00		
				to 02/27/00	
Diagnosis for us	e		Event	abated after use	
Nits in hair			stoppe	d or dose reduced	
			doesn'	t apply	
Lot#	Exp. date		Event	reappeared after	
			reintro	oduction	
NDC # -			doesn'	't apply	
Concomitant med	=				
Nix was used 02/2	26/00 once of	ne b	ottle 2 c	OZ.	
D. Suspect med	lical device	•			
Brand name					
Type of device					
Manufacturer na	me and add	lress		ator of device	
			□ _h	ealth professional	
			user facility		
			distributor		
				ration date	
model #			_		
catalog #			_ If implanted, give date		
serial #					
lot #			_ If exp	planted, give date	
other #					
Device available $\square_{yes} \square_{no}$				turor / /	
Concomitant medical products					
E. Reporter					
Name and addre	SS	p	hone #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to					
$oxed{oxed}_{ m yes}$ $oxed{oxed}_{ m no}$	_			manufacturer	
If you do NOT wai	nt your identi	ty		user facility	
disclosed to the ma			an 🔲	distributor	

A. Patient Inform	ation						
Patient Identifier	Date of birth	Sex	Weight				
108	2/22/77	female	135	lbs			
B. Adverse event	t or product p	roblem					
Advers	Adverse Event & Product Problem						
Outcomes attribut	ted to adverse e	event					
death	□ death □ disability						
☐ life-threatening	□ congenital	anomaly					
$\square_{ m hospitalization}$	required in	ntervention					
other: infestation	on worsened bur	nps on head	d and sore	es			
Date of event 2/27	7/00 Date	of report	2/28/2	2000			
Describe event or	problem						
I have bumps and so	-		a serious				
increase in infestation	on rather than a	decrease					
Relevant tests/labo	oratory data						
Other relevant his	story, including	g preexisti	ng condi	tion			

Triage Unit Sequence #	

C. Suspect medication(s)				
Name: Clear				
Dose, frequency, route use The			rapy d	ates
2oz. 10 days ago		2/17	7/00	4.5
				to 2/27/00
Diagnosis for us	e		Event	abated after use
two oz & removal	cream repea	t	stoppe	d or dose reduced
	•		no	
Lot#	Exp. date		Event	reappeared after
	1			duction
NDC# -	-		yes	
Concomitant me	dical produ	cts		
previos infestatio	n over a year			
	•			
D. Suspect med	dical device	•		
Brand name				
Type of device				
Manufacturer na	ame and add	lress	Oper	ator of device
			$\square_{\rm h}$	ealth professional
				ser facility
				istributor
			\bot	ration date
model #			L.Api.	auton dute
catalog #			If im	planted, give date
serial #			-	
lot #			If exp	olanted, give date
other #			1	
Device available				
□ _{yes} □ _{no}	returned	to m	anufact	urer/_/
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	ss	p	hone #	(781)449-6487
The National Pe	diculosis A	sso	ciation	
P.O. Box 610189	, Newton, M	1A. (02461	
Health professio	nal Occuj	patio	n	Also reported to
	_			manufacturer
			user facility	
disclosed to the ma			an 🔲	distributor

A. Patient Inform							
Patient Identifier	Date of birth	Sex	Weight				
105	05/12/88	female	90 lbs				
B. Adverse event	t or product p	roblem					
	Product Prob	lem					
Outcomes attribut	ted to adverse o	event					
\Box_{death}	disability						
□ life-threatening							
hospitalization	required in	ntervention					
other: none of t							
Date of event 12/9	99-2/00 Date	e of report	2/24/2000				
Describe event or		orreport					
We have used NIX,	_	tea tree and	the				
prescription Lindan							
cleaned with Lysol,	_						
plastic covers. I an	n at my wits end	l.					
Relevant tests/labo	oratory data						
	J-2005-J 20050						
Other relevant his							
None she is the hea			ear infections,				
no major problems.	No nospitaliza	tions.					

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name: lindane				
Dose, frequency	, route use	The	erapy d	ates
2 times	,	12/9		
2 times		12/		to 02/00
Diagnosis for us			Event	abated after use
Diagnosis for us	e			avateu after use d or dose reduced
2 oz				a or dose reduced
	1		no	
Lot #	Exp. date			reappeared after
			reintro	oduction
NDC #			yes	
NDC# -		-4.		
Concomitant me	=			
We used RID AG	_	and	I will ta	ake her to the
doctor if it reoccu	rs again.			
D. Suomost mas	diaal dayia			
D. Suspect med	ilcai device	,		
Brand name				
Type of device Manufacturer na	ame and add	Irece	Oner	ator of device
iviandiactarei in	anic una uac	ii Co.	1 -	ealth professional
				ser facility
				istributor
				ration date
			Expi	ation date
model			- If im	planted, give date
serial #			- '	, ,
lot #			If ex	planted, give date
other #			. -	, ,
Device available	for evaluati	ion?		
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to m	nanufact	turer/_/
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	cc	n	hone #	(781)449-6487
The National Pe		ᆮ		(101)-17-0-101
P.O. Box 610189	· · · · ·			
Health professio ✓ yes □ no	nal Occup	oatio	n	Also reported to
,				manufacturer
If you do NOT wa	•	-		user facility distributor
disclosed to the ma	anufacturer, p	lace	an 🔳	-uisuibutor

	400				
A. Patient Inform	ation				
Patient Identifier	Date of b	irth	Sex	Weight	
103	6-13-88		female	155	lbs
B. Adverse event	or produ	ıct pr	oblem		
	Product	Prob	lem		
Outcomes attribut	ted to adv	erse e	event		
\Box_{death}	\Box_{disab}	oility			
☐ life-threatening	\Box_{cong}	enital	anomaly		
□ hospitalization	\square_{requi}	ired in	tervention		
other:					
Date of event 2-1	7-00	Date	of report	2/21/	2000
Describe event or	problem				
Step Daughter has h		•	•		
rinse to hair, left on					
for 4-1/2 hrs. Next r finding more.	norning, ic	ouna 1	12 five fous	se and stil	I
more.					
Relevant tests/labo	oratory da	ıta			
Other relevant his					
Step-daughter had of January, not sure ho					
She lives with her b					
Dr. and was issued	a perscript				
were told that it wa	l				

Triage Unit Sequence #	

	lication(s)			
Name: lindane				
Also NI	X			
Dose, frequency, route use The		Ther	herapy dates	
shampoo @ 5 day	intervals	1-8-0	00	to
Nix: 1 application				to 2-17-00
Diagnosis for us	e	F	Event	abated after use
Head Lice		S	toppe	d or dose reduced
		1	no	
Lot#	Exp. date		Event	reappeared after
	•			duction
NDC# -	-		yes	
Concomitant me	dical produ	cts		
	•			
D. Suspect med	lical device	9		
Brand name				
Type of device				
3.4 C ·				
Manufacturer na	ime and add	dress	Oper	ator of device
Manufacturer na	me and add	dress	1 —	
Manufacturer na	ame and add	dress	$\Box_{\mathbf{h}}$	ealth professional
Manufacturer na	ame and add	dress		ealth professional ser facility
Manufacturer na	ame and add	dress		ealth professional ser facility istributor
		lress		ealth professional ser facility
model #		lress	□he □u: □d: Expin	ealth professional ser facility istributor ration date
model # catalog #		lress	□he □u: □d: Expin	ealth professional ser facility istributor
model # catalog # serial #		lress	Expir	ealth professional ser facility istributor ration date planted, give date
Manufacturer na model # catalog # serial # lot #		lress	Expir	ealth professional ser facility istributor ration date
model # catalog # serial # lot # other #			Expir	ealth professional ser facility istributor ration date planted, give date
model # catalog # serial # lot # other # D <u>ev</u> ice av <u>ail</u> able	for evaluat	 ion?	Expir If imp	ealth professional ser facility istributor ration date planted, give date
model # catalog # serial # lot # other # Device available yesno	for evaluat	ion?	Expir If imp	ealth professional ser facility istributor ration date planted, give date
model # catalog # serial # lot # other # Device available yesno	for evaluat	ion?	Expir If imp	ealth professional ser facility istributor ration date planted, give date
model # catalog # serial # lot # other # Device available yesno	for evaluat	ion?	Expir If imp	ealth professional ser facility istributor ration date planted, give date
model # catalog # serial # lot # other # Device available	for evaluat	ion?	Expir If imp	ealth professional ser facility istributor ration date planted, give date
model # catalog # serial # lot # other # Device available	for evaluat returned dical produ	ion?	Expir If imp	ealth professional ser facility istributor ration date planted, give date planted, give date urer / /
model # catalog # serial # lot # other # Device available	for evaluat Treturned dical produ	ion? to ma	Expir If imp	ealth professional ser facility istributor ration date planted, give date planted, give date urer / /
model # catalog # serial # lot # other # Device available	for evaluate returned dical products	ion? to ma cts ph	Expir If imp	ealth professional ser facility istributor ration date planted, give date planted, give date urer / /
model #	for evaluate returned dical products ss diculosis A	ion? to ma cts ph associ	Expir If implification and the second of th	ealth professional ser facility istributor ration date planted, give date planted, give date urer /_/
model #	for evaluate returned dical production in the control of the contr	ion? to ma cts ph associ	Expir If implification and the second of th	ealth professional ser facility istributor ration date planted, give date planted, give date urer /_/
model #	for evaluate returned dical products Adiculosis Adiculo	ion? to ma cts ph associ IA. 02	Expir If implification and the second of th	ealth professional ser facility istributor ration date planted, give date planted, give date urer /_/

	-						
A. Patient Inform							
Patient Identifier	Date of birth	Sex	Weight				
102	06/25/90	female	85 I	bs			
B. Adverse event	t or product p	roblem					
Advers	Adverse Event & Product Problem						
Outcomes attribut	ted to adverse o	event					
\Box_{death}	$\Box_{disability}$						
☐ life-threatening	☐ life-threatening ☐ congenital anomaly						
□hospitalization	☐required in	ntervention					
other: headache	es						
Date of event 02/1	15/00 Date	e of report	2/20/200	00			
Describe event or							
after second treatme		couple days	later now				
she is complaining of		1 3					
Relevant tests/labo	oratory data						
Other relevant his	story, including	g preexisti	ng conditio	n			

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: Nix					
Dose, frequency, route use The			nerapy dates		
one 3fl. ounce bot	tle every	02/0	03/00		
week for two wee	-			to 02/13/00	
Diagnosis for us	e		Event	abated after use	
lice and nits			stopped or dose redu		
			yes		
Lot #	Exp. date		Event	reappeared after	
	1			duction	
			i ciiiti (auchon	
NDC# -	-		yes		
Concomitant me	dical produ	cts			
	-				
D. Suspect med	dical device				
Brand name	arour dovio				
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
				ealth professional	
				ser facility	
			distributor		
				ration date	
			Expii	auon uate	
model # catalog #			- If im	planted, give date	
serial #			- '	, 8	
lot #			If ext	planted, give date	
other #				Junica, gryc autc	
Device available					
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to m	anufact	urer/_/	
Concomitant me	dical produ	cts			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pe	diculosis A	sso	ciation		
P.O. Box 610189, Newton, MA. 02461					
Health professio	nal Occup	patio	n	Also reported to	
\bigvee_{yes} \square_{no}	_			manufacturer	
If you do NOT wa	·			user facility	
disclosed to the ma			an 🔲	□distributor	

A. Patient	Inform	ation						
Patient Id	entifier	Date of b	irth	Sex	Weight			
	101	05/02/19	99	female	13	lbs		
B. Advers	e even	t or prod	uct p	roblem				
	Adverse Event & Product Problem							
Outcomes attributed to adverse event								
death disability								
□ life-thr	☐ life-threatening ☐ congenital anomaly							
\Box_{hospita}	llization	∠ requ	ired ir	ntervention				
other:								
Date of ev	ent 08/	15/1999	Date	of report	2/20/2	2000		
Describe e		_	•					
Allergic res	sponse, i	nconsolab	le cryi	ng, rash, hi	ves, swell	ing		
D.1	4 - /I - I-		- 4 -					
Relevant to	ests/labo	oratory da	ata					
Other rele	vant his	story, inc	luding	preexisti	ng condi	tion		
	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		5 Province	g			

Triage Unit Sequence #	

C. Suspect medication(s)					
Name:					
Elimite					
Dose, frequency,	, route use	rapy d	ates		
one treatment per			15/1999		
one treatment per carattempt 100			to 08/15/1999		
Diagnasis for us	0	Event			
Diagnosis for use			Event abated after use stopped or dose reduced		
scabies			stopped of dose reduced		
			yes		
Lot #	Exp. date		Event	reappeared after	
			reintroduction		
NDC #			yes		
NDC# -	-				
Concomitant me	-				
		ctio	ı. Scab	ies symptoms still	
continue today, 02	2/18/2000				
D. Suspect med	dical device)			
Brand name					
Type of device			1.		
Manufacturer na	ame and add	lress		ator of device	
			□h	ealth professional	
			user facility distributor		
			Expi	ration date	
model #			- Te :	ulantad atus data	
catalog #			- 11 11M _.	planted, give date	
serial # lot #			TC	.14.1	
other #			_ II exp	planted, give date	
	C14				
Device available $\square_{\mathrm{yes}} \square_{\mathrm{no}}$				turor / /	
Concomitant me				turer//	
	arear produ				
E. Reporter					
Name and addre	SS	p	hone #	(781)449-6487	
The National Pe	diculosis A	sso	ciation		
P.O. Box 610189	, Newton, M	1A. (02461		
Health professio	nal Occup	patio	n	Also reported to	
	_			manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma			an 🔲	□distributor	

A. Patient Inform	ation							
Patient Identifier	Date of birth	Sex	Weight					
98	1/19/86	female	124	lbs				
B. Adverse event	or product p	roblem						
Product Problem								
Outcomes attributed to adverse event								
death disability								
☐ life-threatening ☐ congenital anomaly								
□hospitalization	required in	ntervention						
other:								
Date of event 20/0	00/ Date	e of report	2/18/2	2000				
Describe event or	problem							
none of the shampoo				erics				
are not working. Li leaving on for a prob		present ev	en after					
leaving on for a prof	ionged time.							
Relevant tests/labo	oratory data							
Other relevant his	story, including	g preexisti	ng condi	tion				
none								

Triage Unit Sequence #	

C. Suspect med							
Name: generic li	ice shampoo						
lindane							
Dose, frequency,	, route use	The	Therapy dates				
once a week, sometimes 19			9				
every 2 weeks				to 2000			
Diagnosis for use			Event	abated after use			
e e			stopped or dose reduce				
I'm not sure							
-			no				
Lot#	Exp. date			reappeared after			
			reintroduction				
NDC #			doesn'	t apply			
NDC# -	-						
Concomitant me	dical produ	cts					
D. Suspect med	lical device	•					
Brand name							
Type of device							
Manufacturer na	ame and add	lress	Oper	ator of device			
				ealth professional			
			user facility				
			distributor				
			Expi	ration date			
model #							
catalog #			_ If implanted, give date				
serial #			. L				
lot #			_ If exp	planted, give date			
other #							
Device available $\square_{yes} \square_{no}$				urer / /			
Concomitant me							
F							
E. Reporter							
Name and addre	ss	p	hone #	(781)449-6487			
The National Pe	diculosis A	sso	ciation				
P.O. Box 610189	, Newton, M	ΙΑ. (02461				
Health professio	-	atio	on	Also reported to			
$\mathbf{v}_{\mathrm{yes}}$ \square_{no})			manufacturer			
If you do NOT wa	nt your identi	ty		user facility			
lisclosed to the manufacturer, place an distributor							

A. Patient I		-4:						
			a	*** * * * .				
Patient Ider		Date of birth	Sex	Weight				
	94	6/94	female	65 lbs				
B. Adverse	event	or product p	roblem					
		Product Pro	blem					
Outcomes a	ttribut	ted to adverse	event					
\Box_{death}	death disability							
□ life-threa	☐ life-threatening ☐ congenital anomaly							
□hospitali	zation		ntervention					
other:		•						
Date of ever	nt 7/99	Dat	te of report	2/15/2000				
Describe eve	ent or							
		festation over t	he last six n	onths. Has				
		e lice and nits.						
		iffocating treati						
this home ha	ve not	had lice please	help!					
Relevant tes	ts/labo	oratory data						
Other releva	ant his	story, includir	g preexisti	ng condition				
none			0 F- 3034.	ð				

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: Clear					
kwell, Ni	x, Rid				
Dose, frequency,	route use	The	erapy dates		
1 time per per or i	nore	7/98			
			2/00		
Diagnosis for use			Event abated after us	se	
live head lice and nits			stopped or dose redu	ced	
			doesn't apply		
Lot #	Exp. date		Event reappeared aft	er	
	_		reintroduction		
NDC# -	-		yes		
Concomitant me	dical produ	cts			
vaseline, mayiona	se, quene He	lene,			
D. Suspect med	lical device)			
Brand name					
Type of device	me and add	Inocc	Operator of device		
Manufacturer na	ime and add	ıress	Operator of device		
			health profession	ıal	
			user facility distributor		
"			Expiration date		
model			If implanted, give d		
serial #			- F , g	ate	
				ate	
IUL #			If explanted, give da		
lot # other #			If explanted, give da		
other # Device av <u>ail</u> able	f <u>or</u> evaluat				
other # Device available yes no	for evaluat	to m	anufacturer _ / _/_		
other # Device av <u>ail</u> able	for evaluat	to m	anufacturer _ / _/_		
other # Device available yes no	for evaluat	to m	anufacturer _ / _/_		
other # Device available	for evaluat	to m	anufacturer _ / _/_	ate	
other # Device available yes no Concomitant me E. Reporter	for evaluat returned dical produ-	to m	hone # (781)449-648	ate	
other # Device available yes no Concomitant me E. Reporter Name and addre	for evaluate returned dical products	to m cts	hone # (781)449-648'	ate	
other # Device available	for evaluate returned dical production production for the control of the control	p.	hone # (781)449-6486 ciation 02461 Also reported	7 1 to	
other # Device available	for evaluating returned dical productions of the second se	passocianical	hone # (781)449-648' ciation	77	

A. Patient Inform	ation							
Patient Identifier	Date of birth	Sex	Weight					
89	07/07/92	female	45	lbs				
B. Adverse event	t or product p	roblem						
Advers	Adverse Event & Product Problem							
Outcomes attribut	ted to adverse	event						
\Box_{death}	death disability							
☐ life-threatening	☐ life-threatening ☐ congenital anomaly							
hospitalization	required in	ntervention						
other: Scalp De	ermatitis							
Date of event 02/0	01/2000 Date	e of report	2/12/2	2000				
Describe event or	problem							
Constant treatment	_							
School will not remain keeps getting reinver								
school and will not								
no head lice.	send her back as	atin sensor	cuir guara	11100				
Relevant tests/labo	oratory data							
Other relevant his	story, including	g preexisti	ng condi	tion				

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Nix					
R & C					
Dose, frequency, route use Th			herapy dates		
Weekly as described on the		11/03/99			
product label.				to 02/10/2000	
Diagnosis for use			Event abated after use		
Caused scalp irita		stopped or dose red		d or dose reduced	
soreness.			yes		
 Lot #	Exp. date			1 64	
Lot II	Lap. date			reappeared after	
		1	reintroduction		
NDC# -	_		yes		
Concomitant me	dical produ	cts			
Olive oil	•				
D. Suspect med	dical device)			
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
			\square_{h}	ealth professional	
				ser facility	
			distributor		
			Expir	ation date	
model #					
catalog #			If im	planted, give date	
serial #					
lot #			If exp	olanted, give date	
other #					
Device available		ion?			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			nufact	urer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	SS	ph	one#	(781)449-6487	
The National Pe	diculosis A	ssoci	iation		
P.O. Box 610189	, Newton, M	1A . 0	2461		
Health professio	nal Occuj	oation	1	Also reported to	
\mathbf{V}_{yes} \square_{no}				manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma	-	-	ın 🔲	distributor	

	acc					
A. Patient Inform						
Patient Identifier	Date of b	irth	Sex	Weight		
88	0-00-92		female	72	lbs	
B. Adverse event	or produ	ıct pı	oblem			
	Advers	se Eve	ent			
Outcomes attribut	ed to adv	erse e	event			
death	disat	oility				
☐ life-threatening	\Box_{cong}	enital	anomaly			
$\Box_{ m hospit}$ alization	□requi	ired in	tervention			
other: doctor co	onfirmed a	dvers	e			
Date of event 2-10	0-00	Date	of report	2/11/	2000	
Describe event or	problem					
She was skating yes	_	d got a	muscle sp	oasm in h	er	
neck headache an					ıny	
NIX treatments. Do				remely		
swollen glands. Pu	t her on M	lotrin	for pain.			
Relevant tests/labo	oratory da	ıta				
Other relevant his	tory, incl	uding	g preexisti	ing condi	ition	
General health okay with normal flu and colds. Doctor						
gave her the Motrin	n. WE hav	e spra	ayed with	the NIX s	pray	
quite a bit in the beg	ginning sin	ce Se _j	ptember an	d Octobe	r.	

Triage Unit Sequence #	

C. Suspect me	dication(s)					
Name: Nix						
Nix spray at the same time						
Dose, frequency, route use Therapy dates				ates		
many times		9-00)-99			
			to 2-10-00			
Diagnosis for us	se		Event :	abated after use		
head lice			stopped or dose reduced			
nead nee			no			
Lot#	Exp. date		Event.	moonnoomed after		
	Zapr unit			reappeared after oduction		
NDC# -	-		doesn'	t apply		
Concomitant me	edical produ	cts				
motrin for pain a doctor	ssociated with	h this	s event	prescribed by		
D. Suspect me	dical device	.				
Brand name						
Type of device						
Manufacturer n	ame and add	lress	Oper	ator of device		
				ealth professional		
			user facility			
			distributor			
			Expi	ration date		
model #			_			
catalog #			If im	planted, give date		
serial #						
lot #			If exp	planted, give date		
other #						
Device available for evaluation? yes no returned to manufacturer/_/						
Concomitant mo	edical produ	cts				
E. Reporter						
Name and addre	ess	p	hone #	(781)449-6487		
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
Health profession ✓ yes n		patio	n	Also reported to manufacturer		
If you do NOT wa	ınt your identi	ity		user facility		
disclosed to the m			an 🔲	distributor		

A. Dationt le		-1!				
A. Patient Ir			~			
Patient Iden		Date of birt! 11-17-75		_	Weight	11
D. Ashaana	87		femal		172	lbs
B. Adverse	even			n		
		Adverse I				
Outcomes at	tribut					
death		∐disabilit	•			
☐ life-threa	Ū			-		
hospitaliz			interven	tion		
other: de	ath in	unborn child				
Date of even	t 11-9	9-99 D a	ate of rep	port	2/10/2	2000
Describe eve	nt or	problem				
was using lice						here
were many de	efects	that just don't	happen	toge	ther.	
Relevant test	ts/labo	oratory data				
Other releva	nt his	story, includ	ing pree	xisti	ng condi	tion
I						

Triage Unit Sequence #	

C. Suspect me	dication(s)			
Name: Kwell				
RID, N	IX, generic bi	ands	s, and s	prays
Dose, frequency	, route use	The	erapy d	ates
used atleast 2 tim	nes a month	6-98	3	
				to 10-99
Diagnosis for u	se		Event	abated after use
stepdaughter had	lice, was usin	ıg	stoppe	d or dose reduced
as cure			doesn	t apply
Lot#	Exp. date			reappeared after
	1			duction
NDC# -	-		doesn	t apply
Concomitant me	edical produ	cts		
D. Suspect me	dical device	•		
Brand name				
Type of device				
Manufacturer n	ame and add	lress	Oper	ator of device
			\square_{h}	ealth professional
			\square_{u}	ser facility
			\square_{d}	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #			-	
lot #			_ If exp	planted, give date
other #				
Device available				
	returned		nanufact	urer/_/
Concomitant m	edical produ	cts		
E. Reporter				
Name and addr	ess	p	hone #	(781)449-6487
The National P	ediculosis A	sso	ciation	
P.O. Box 61018	9, Newton, M	ΙΑ. (02461	
Health profession	onal Occur	oatio	n	Also reported to
$\mathbf{\nabla}_{\mathrm{yes}}$ $\mathbf{\square}_{\mathrm{n}}$				manufacturer
If you do NOT wa		ity		user facility
disclosed to the m	•	•	an 🔲	distributor

A. Patient Inform	ation							
Patient Identifier	Date of bi	rth	Sex	Weight				
83	1/26/93		female	69	lbs			
B. Adverse event	or produ	ct p	roblem					
Advers	e Event &	Prod	luct Proble	m				
Outcomes attribut	ted to adve	rse e	event					
\Box_{death}	□disabi	lity						
☐ life-threatening	☐ life-threatening ☐ congenital anomaly							
□ hospitalization	□requir	ed ir	ntervention					
other: sores on	head from t	reati	ment					
Date of event 1/20	000	Date	of report	2/7/	2000			
Describe event or	_							
got nix and used it a								
home 2 days later w	-							
back to school, retro head from the treatr	-	s rate	er. sne nas s	sores on r	ier			
nead from the treati	nent							
Relevant tests/labo	oratory dat	a						
	, ,							
Other relevant his	storv, inclu	dins	preexisti	ng condi	tion			
	, , , , , ,		91	8 ** **				

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name: Nix				
Dose, frequency, route use The			rapy d	ates
2 bottles 7 days a	part	1/20	000	to
				1/2000
Diagnosis for us	e		Event	abated after use
school found then	ı		stoppe	d or dose reduced
			no	
Lot#	Exp. date		Event	reappeared after
				duction
			WAS	
NDC# -	-		yes	
Concomitant me	dical produ	cts		
have used cream r	inses left on	hair	over nig	ght because of the
sores on her head,	this is a dail	y thi	ing sinc	e if we do not do
this we find lice of	n her scalp			
D. Suspect med	dical device	•		
Brand name				
Type of device				
Manufacturer na	ame and add	lress	Oper	ator of device
			\square_{h}	ealth professional
				ser facility
				istributor
			_	ration date
model #			Lapi	auton dute
model # catalog #			If im	planted, give date
serial #			- '	, , ,
lot #			If ext	planted, give date
other #			'	, , , , , , , , , , , , , , , , , , , ,
Device available	for evaluati	ion?		
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$				urer//
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	SS	p	hone #	(781)449-6487
The National Pediculosis Association				
P.O. Box 610189	, Newton, M	1A. (02461	
Health professio	nal Occuj	patio	n	Also reported to
)			manufacturer
If you do NOT wa	nt your identi	ity		user facility
disclosed to the ma	-	-	an 🔳	□distributor

A. Patient I					
Patient Ider	ıtifier	Date of birth	Sex	Weight	
	80	09/24/85	female	105	lbs
B. Adverse	event	or product p	roblem		
		Product Prol	olem		
Outcomes a	ttribut	ted to adverse	event		
\Box_{death}		disability			
□ life-threa	tonina		anomaly		
I —	_		-		
□hospitali	zation	required i	ntervention		
other:					
Date of ever	nt 01/0	01/98 Dat	e of report	2/3/2	2000
Describe eve	ent or	problem			
	_	r over one year	_	•	sts.
	-	nd myself have	_	-	
		eister comb help			
	•	bings with it w	e both have	nits. My	7
husband has	not bee	en infested.			
Relevant tes	ts/labo	oratory data			
Other releva	ant his	story, includin	g preexisti	ng condi	tion
I					

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name: lindane				
nix, olive	e oil, tea tree	oil		
Dose, frequency,	, route use	The	rapy d	ates
multiple		01-0)1-98	
				to 02/04/00
Diagnosis for us	e		Event	abated after use
head lice infestation				d or dose reduced
nead nee nnestatio	511			t apply
 Lot #	Exp. date			
Lot #	Exp. date			reappeared after
			reintro	oduction
NDC# -	_		doesn'	t apply
Concomitant me	dical produc	ets		
multiple	produ			
munipic				
D. Suspect med	dical device	•		
Brand name				
Type of device				
Manufacturer na	ame and add	lress	Oper	ator of device
			$\square_{\rm h}$	ealth professional
user facility			ser facility	
			\square_{d}	istributor
			Expir	ration date
model #				
catalog #			If im	planted, give date
serial #				
lot #			If exp	planted, give date
other #				
Device available				
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$				urer//
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	ss	p	hone #	(781)449-6487
The National Pediculosis Association				
P.O. Box 610189, Newton, MA. 02461				
Health professio	nal Occup	oatio	n	Also reported to
$\mathbf{v}_{\mathrm{yes}}$ \mathbf{v}_{no}	_			manufacturer
If you do NOT wa	nt your identi	ty		user facility
disclosed to the ma			on 🔲	distributor

A. Patient Inform		-		
Patient Identifier		Sex	Weight	
78	19/83/	female	170	lbs
B. Adverse event				
Advers	e Event & Prod	luct Proble	em	
Outcomes attribut	ted to adverse o	event		
\Box_{death}	disability			
☐ life-threatening	□ congenital	anomaly		
$\square_{ m hospitalization}$	required in	ntervention		
other: boils on	scalp			
Date of event 1-20	000 Date	e of report	2/2/2	2000
Describe event or				
have 2 childten, hav	_			
children at least 5 ti	mes this school			
year completely ren				
cleaned entire house				
two days, after sch they go back to sch				
weeks they have lice				
weeks they have her	e ugum.			
Relevant tests/labo	oratory data			
Other relevant his	story, including	g preexisti	ng condi	tion
	•	3 L	8	

Triage Unit Sequence #	

mayonaise, rid, nix, olive oil, clear Dose, frequency, route use every 7 to 10 days each time Therapy dates 8/1999 to 1/2000	50
mayonaise, rid, nix, olive oil,clear Dose, frequency, route use every 7 to 10 days each time 8/1999 to 1/2000 Diagnosis for use lice removal Event abated after use stopped or dose reduced to the stopped or dose re	60
Dose, frequency, route use every 7 to 10 days each time 8/1999 to 1/2000 Diagnosis for use lice removal Event abated after ustopped or dose reduced to the stopped or dose reduced to th	50
every 7 to 10 days each time 8/1999 to 1/2000 Diagnosis for use lice removal Event abated after ustopped or dose reductions.	50
Diagnosis for use lice removal Event abated after u stopped or dose redu	50
Diagnosis for use lice removal Event abated after use stopped or dose redu	60
lice removal stopped or dose redu	co
lice removal stopped or dose redu	SC
	ced
T 4 //	
Event reappeared at	er
reintroduction	
NDC# yes	
Concomitant medical products	
Concommunit medicar products	
D. Suspect medical device	
Brand name	
Type of device	
Manufacturer name and address Operator of device	
health professio	nal
user facility	liai
distributor	
Expiration date	
model # If implanted, give of	late
serial #	
lot # If explanted, give d	ate
other #	
Device available for evaluation?	
yes no returned to manufacturer/_/_	
	_
	_
Concomitant medical products	
Concomitant medical products E. Reporter	7
Concomitant medical products E. Reporter Name and address phone # (781)449-648	7
Concomitant medical products E. Reporter Name and address phone # (781)449-648 The National Pediculosis Association	7
E. Reporter Name and address The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461	
Concomitant medical products E. Reporter Name and address The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461 Health professional Occupation Also reporter	d to
Concomitant medical products E. Reporter Name and address The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461 Health professional Occupation Also reporter Also reporter	d to

A. Patient Informa						
Patient Identifier	Date of birth	Sex	Weight			
76	02/02/90	female	65 lbs			
B. Adverse event						
	e Event & Prod		e m			
Outcomes attribut	_	event				
□death	□disability					
	life-threatening congenital anomaly					
□hospitalization	☐ required in	ntervention				
other: Hives						
Date of event 01/2	28/00 Date	e of report	2/2/2000			
Describe event or My daughter broke neck and shoulders. affected the lice	out in hives (an Needless to say	-	_			
Relevant tests/labo		g preexisti	ing condition			
No pre existing med	dical conditions					

Triage Unit Sequence #	

C. Suspect med	dication(s)			
Name:				
All OTC	shamppos a	nd s	prays, a	also Lindane
Dose, frequency,	, route use	The	rapy d	ates
As directed on the labels 09-9				
				to 02/02/00
Diagnosis for us	0		Event	abated after use
?	C			d or dose reduced
?				a or aose readeed
			yes	
Lot#	Exp. date			reappeared after
			reintro	oduction
NDC# -			yes	
	3112			
Concomitant me	=			
Often this school	year, average	of o	once to	twice a month
5.0				
D. Suspect med	lical device	•		
Brand name				
Type of device	1 1		10	4 63 .
Manufacturer na	ime and add	iress		ator of device
				ealth professional
				ser facility istributor
			Expir	ration date
model #			If im	planted, give date
catalog #			- 111 1111	pianieu, give uate
serial # lot #			Tf over	olanted, give date
other #			- III ext	nameu, give date
Device available	for evaluati	on?		
				turer / /
Concomitant me				
E Poporter				
E. Reporter Name and addre	ee.		horo#	(781)449-6487
The National Pe		Ĺ		(101)++2-0+01
P.O. Box 610189				
			1	43
Health profession ✓ yes □nc	_	patio	n	Also reported to
-				manufacturer user facility
If you do NOT was				distributor
disclosed to the ma	ınutacturer, p	ıace	an 🔳	

A. Patient Ir	-f	otion		
			G	***
Patient Iden	55	Date of birth 9-30-92		Weight
D. Advaraa			female	65 lbs
b. Adverse	eveni	or product		
		Product Pro		
l —	tribut	ted to adverse		
death		☐ disability		
☐ life-threa	_		al anomaly	
hospitaliz	zation	☐ required	intervention	
other:				
Date of even	t 199	9-2000 Da	te of report	1/25/2000
Describe eve	nt or	problem		
		ne a note sayin	_	
		everything.the		
		e tried Rid, Nix		store brands
or treatments	mey	just keep comi	ng back.	
Relevant test	ts/labo	oratory data		
Other releva	nt his	story, includii	ng preexisti	ng condition

Triage Unit Sequence #	

0.0	I' (' / -)			
C. Suspect med	lication(s)			
Name: Clear				
Kwell, N	lix, Mayonna	aise,	Rid, sto	ore brands
Dose, frequency	route use	The	rapy d	ates
once every 7-10 d	ays as	199	9	to
directed				to 2000
Diagnosis for us	e		Event	abated after use
no help		stoppe	d or dose reduced	
			doesn'	t apply
Lot#	Exp. date		Event	reappeared after
			reintroduction	
			yes	
NDC# -	-		303	
Concomitant me	dical produ	cts		
none				
D. Suspect med	dical device	•		
Brand name				
Type of device				
Manufacturer na	me and add	lress	Oper	ator of device
			\square_{h}	ealth professional
				ser facility
			\square_{d}	istributor
			Expi	ration date
model #				
catalog #			If im	planted, give date
serial #			. L	
lot #			_ If exp	planted, give date
other #				
Device available □ _{yes} □ _{no}				urer / /
Concomitant me	dical produ	cts		
E. Reporter				
Name and addre	ss	p	hone #	(781)449-6487
The National Pe	diculosis A	sso	ciation	
P.O. Box 610189	, Newton, M	IA.	02461	
Health professio	nal Occup	oatio	n	Also reported to
$\mathbf{V}_{\mathrm{yes}} \square_{\mathrm{no}}$)			manufacturer
If you do NOT wa	nt your identi	ty		user facility
disclosed to the ma			an 🔳	□distributor

A Detiont l	eform	otion				
A. Patient II			~			
Patient Iden		Date of birth		Weight	,,	
	54	3/21/91	female	64	lbs	
B. Adverse	even	or product				
		Product Pro				
_	ttribut	ted to adverse				
death		☐ disability				
	☐ life-threatening ☐ congenital anomaly					
hospitali	zation	☐ required	intervention			
other:						
Date of even	t 1/24	4/00 Da	te of report	1/24/2	2000	
Describe eve	ent or	problem				
the products	simply	y do not work				
Relevant tes	ts/labo	oratory data				
Other releve	ant his	story, includi	na proovieti	na condi	tion	
Other releva	ant ms	story, includi	ng preexisu	ng conai	11011	
I						

Triage Unit Sequence #	

C. Suspect med	lication(s)				
Name: lindane	(0)				
, unice influence					
Dose, frequency, route use Th			erapy dates		
			20/99	ates	
directions, used 3t		1 2/2	20/99	to	
				1/24/99	
Diagnosis for us	e		Event abated after use		
to kill headlice			stoppe	d or dose reduced	
			doesn'	t apply	
Lot#	Exp. date		Event	reappeared after	
				duction	
			doesn't apply		
NDC# -	-		doesii	с аррту	
Concomitant me	dical produ	cts			
D. Suspect med	dical device	•			
Brand name					
Type of device			_		
Manufacturer na	me and add	lress	Oper	ator of device	
			\square_{h}	ealth professional	
user facility					
			\square_d	istributor	
			Expir	ration date	
model #			_		
catalog #			_ If im	planted, give date	
serial #			- \coprod		
lot #			_ If exp	planted, give date	
other #					
Device available $\square_{\text{yes}} \square_{\text{no}}$				urer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	ss	p	hone #	(781)449-6487	
The National Pe	diculosis A	ssoc	ciation		
P.O. Box 610189	, Newton, M	ΙΑ. (02461		
Health professio	nal Occuj	oatio	n	Also reported to	
$\mathbf{v}_{\mathrm{yes}} = \mathbf{v}_{\mathrm{no}}$)			manufacturer	
If you do NOT wa	nt your identi	ity		user facility	
disclosed to the ma	ınufacturer, p	lace	an 🔳	□distributor	

A. Patient Inform	ation						
Patient Identifier	Date of birth	Sex	Weight				
53	7/8/92	female	48	lbs			
B. Adverse even	t or product p	roblem					
Product Problem							
Outcomes attribut	ted to adverse	event					
death	disability						
☐ life-threatening ☐ congenital anomaly							
hospitalization	required in	ntervention					
other:							
Date of event 8/9	9-1/00 Dat	e of report	1/24/2	2000			
Describe event or	problem						
Head lice I CANNO							
family beach trip in	-			to:			
rid her of them sinc		EVERYTH	ING				
physically possible	:!						
Polovent tests/lebe	anatany data						
Relevant tests/lab	oratory uata						
Other relevant his	story includin	a proovieti	na condi	tion			
Other relevant his	story, includin	g pi cexisu	ng conun	ши			

C. Suspect medication(s)					
Name:					
Kwell, Nix, Mayo, tea tree oil, now this totalh					
Dose, frequency, route use The			rapy d	ates	
as indicated since	initial	8/25	5/99	to	
outbreak				to 1/21/2000	
Diagnosis for use			Event abated after use		
head lice			stoppe	d or dose reduced	
			no		
 Lot #	Erm data				
Lot#	Exp. date			reappeared after	
			reintroduction		
NDC# -	_		yes		
	- 4:1 ?	.4.			
Concomitant me	uicai produ	cts			
D. Suspect med	lical device)			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			_	ealth professional	
				ser facility	
			distributor		
			Expii	ration date	
model #			- Te :	nlantad aire data	
catalog #			- III IIII	planted, give date	
serial #			-		
lot # other #			- If exp	olanted, give date	
Device available $\square_{\text{yes}} \square_{\text{no}}$			anufact	urer / /	
Concomitant medical products					
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189	, Newton, M	1A. (02461		
Health professio	nal Occuj	oatio	n	Also reported to	
				manufacturer	
If you do NOT want your identity user facility				user facility	
disclosed to the ma			an 🔲	distributor	

A. Patient I	oform	otion					
		Date of birth	Sex	Waight			
Patient Ider	52	9/26/65	female	Weight 145	lba		
R Adverse		or product p		143	lbs		
b. Auverse	eveni	Product Prob					
0.4							
	ttribut	ted to adverse	event				
	death disability						
	☐ life-threatening ☐ congenital anomaly						
□hospitali	zation	☐ required in	ntervention				
other:							
Date of even	t 1/99	Date	e of report	1/24/2	2000		
Describe eve	ent or	problem					
-		nave been havin	-				
		ems like foreve	r'				
		single different					
		nt that is found K-Mart and dru		iust do			
not know wh			15 Store. 1	ust do			
Relevant tes	ts/labo	oratory data					
Other releva	ant his	story, includin	g preexisti	ng condi	tion		

Triage Unit Sequence #	

	C. Suspect medication(s)					
Name: Nix						
Rid, kwell Rite Aid						
Dose, frequency, route use Th			rapy d	ates		
Every two weeks	for over 3	8/99)	4-		
months				to 1/00		
Diagnosis for us	e		Event abated after use			
headlice, 7 childre	n		stoppe	d or dose reduced		
mom and dad			no			
Lot #	Exp. date		Event i	reappeared after		
				duction		
NDC# -	-		yes			
Concomitant me	dical produ	cts				
I don't know the d	lates					
D. Suspect med	lical device	•				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
	health professional					
user facility						
				ser facility		
model #				ser facility istributor		
model # catalog #			Expin	ser facility istributor		
catalog # serial #			Expin	ser facility istributor ration date		
catalog # serial # lot #			Expin	ser facility istributor ration date		
catalog # serial #			Expin	ser facility istributor ration date planted, give date		
catalog # serial # lot # other # Device av <u>ail</u> able	for evaluat	ion?	Expired If important If exp	ser facility istributor ration date planted, give date planted, give date		
catalog # serial # lot # other # Device available yes no	for evaluat	ion?	Expir If imp	ser facility istributor ration date planted, give date planted, give date		
catalog # serial # lot # other # Device av <u>ail</u> able	for evaluat	ion?	Expir If imp	ser facility istributor ration date planted, give date planted, give date		
catalog # serial # lot # other # Device available yes no	for evaluat	ion?	Expir If imp	ser facility istributor ration date planted, give date planted, give date		
catalog # serial # lot # other # Device available	for evaluat returned dical produ	ion?	Expir If imp	ser facility istributor ration date planted, give date planted, give date		
catalog # serial # lot # other # Device availableyesno Concomitant me	for evaluat returned dical produ	ion? to m cts	Expiration of the state of the	ser facility istributor ration date planted, give date planted, give date urer/_/		
catalog # serial # lot # other # Device available	for evaluating returned dical products	ion? to m cts	Expiration	ser facility istributor ration date planted, give date planted, give date urer/_/		
catalog #	for evaluating returned dical productions of the control of the co	pion? pix.ssoc.	Expired to the state of the sta	ser facility istributor ration date planted, give date planted, give date urer _/_/ (781)449-6487		
catalog #	for evaluate returned dical production for evaluate returned dical production for evaluate returned dical production for evaluate returned for evaluate re	picts piA. (capatio	Expired to the state of the sta	ser facility istributor ration date planted, give date planted, give date urer/_/ (781)449-6487		

	_			
A. Patient In				
Patient Ident	ifier	Date of birth	Sex	Weight
	23	12/10/93	female	40 lb
B. Adverse	event	or product p	roblem	
A	dvers	e Event & Pro	duct Proble	em
Outcomes att	ribut	ted to adverse	event	
\Box_{death}		disability		
□ life-threat	ening	_		
hospitaliz			ntervention	
other:	ution	required	inci vention	
Date of event	11/0	98/ D at	e of report	1/15/2000
			e of report	1/13/2000
Describe ever		scalp and recu	rring infacto	tions
Severe burns (m the	scarp and recu	iring imesta	HOHS
D. 1	7. 1	4 14		
Relevant tests	s/lab(oratory data		
Other releva	nt his	story, includin	g preexisti	ng condition
None				

Triage Unit Sequence #	

<u> </u>				•	
C. Suspect med	lication(s)				
Name: generic pyrethrin					
rid and Nix have been used also					
Dose, frequency,	route use	The	rapy d	ates	
Гwo shampoos		11/9	8	4-	
				to 1/00	
Diagnosis for us	e]	Event	abated after use	
Removal of head l		t	stoppe	d or dose reduced	
removing comb			no		
Lot#	Exp. date	_	Cront.	mannaged after	
200	Zinpr date			reappeared after oduction	
				duction	
NDC# -	-		yes		
Concomitant me	dical produ	cts			
D. Suspect med	lical device	;			
Brand name					
Type of device			1_		
Manufacturer na	ime and add	lress	1 —	ator of device	
			l IIII	ealth professional	
			l □u	ser facility istributor	
1.1 #			Expii	ration date	
model # catalog #			If im	planted, give date	
serial #				, ,	
lot #			If exp	olanted, give date	
other #					
Device available					
□ _{yes} □ _{no}			anufact	urer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	SS	pł	one#	(781)449-6487	
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	I A. 0	2461		
Health profession				Also reported to	
$\mathbf{V}_{\mathrm{yes}}$ \mathbf{I}_{no}				manufacturer	
If you do NOT war	nt your identi	ty		user facility	
disclosed to the ma	-	-	an 🔳	□distributor	

A. Patient Inform	ation							
Patient Identifier	Date of birth	Sex	Weight					
22	10/11/90	female	90	lbs				
B. Adverse event	t or product p	roblem						
	Product Problem							
Outcomes attribut	ted to adverse o	event						
death	disability							
☐ life-threatening	Congenital	anomaly						
$\square_{ m hospitalization}$	☐required in	ntervention						
other:								
Date of event 01/1	14/00 Date	of report	1/15/2	2000				
Describe event or	problem							
this is her 7th year				;				
never had a problem	-							
times: We have use going to cut her hair								
oil extract	i shorter and try	the tea on	silampoo	una				
Relevant tests/labo	oratory data							
Other relevant his	story, including	g preexisti	ng condi	tion				

C. Suspect medication(s)					
Name: Clear					
kwell, ric	l, generic				
Dose, frequency, route use The		The	rapy d	ates	
every 4-7 days		1101	199	to	
				to 011400	
Diagnosis for use			Event :	abated after use	
lice			stopped or dose reduce		
пес			doesn't apply		
Lot #	Exp. date		Event	reappeared after	
	F			duction	
		ľ			
NDC# -	-		doesn'	t apply	
Concomitant me	dical produ	cts			
	1				
D. Suspect med	dical device				
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			1 —	ealth professional	
			user facility		
			distributor		
			Expiration date		
			Expii	ation date	
model # catalog #			If im	planted, give date	
serial #			· '	,, ,	
lot #			If evr	planted, give date	
other #			The Car	Junicea, give aute	
Device available	for evaluati	ion?			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$			anufact	urer//	
Concomitant me					
-					
E. Reporter					
Name and address phone # (781)449-6487					
The National Pe	diculosis A	ssoc	iation		
P.O. Box 610189	, Newton, M	I A. (02461		
Health professio	nal Occup	atio	n	Also reported to	
$\mathbf{v}_{\mathrm{yes}} = \mathbf{v}_{\mathrm{no}}$)			manufacturer	
If you do NOT was	nt your identi	ty		user facility	
disclosed to the ma	-	-	an 🔲	□distributor	

A. Patient	Inform	ation				
Patient Id	entifier	Date of b	irth	Sex	Weight	
	18	05-03-93	3	male	52	lbs
B. Advers	e event	or produ	uct pi	oblem		
		Product	Prob	lem		
Outcomes	attribut	ted to adv	erse e	event		
death		∐disat	oility			
∐life-thre	eatening	— ~		anomaly		
	lization	□requi	ired in	tervention		
other:						
Date of ev	ent 12/2	22/99	Date	of report	1/11/2	2000
Describe e	vent or	problem				
Our son wa	s treated	13 times w	vith N	ix then tw	ice with	
lindane .						
Relevant to	ests/labo	ratory da	ata			
0411-	41.*	4				4
Other rele	vant his	story, incl	luding	g preexisti	ng condi	tion

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Nix					
lindane					
Dose, frequency, route use Therapy dates				ates	
		12/2	2/22/99		
			to 1/10/00		
Diagnosis for us	e		Event abated after use		
head lice			stopped or dose reduced		
	nead nee		doesn't apply		
Lot #	Exp. date				
Lot "	Lap. date			reappeared after duction	
				duction	
NDC# -	-		yes		
Concomitant me	dical produ	cts			
Rinsed with 50/50	vinegar and	wat	er solut	ion prior to	
applying lindane.					
D. Suspect med	lical device)			
Brand name					
Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
				ealth professional	
				ser facility	
			\square_{d}	istributor	
			Expi	ation date	
model #					
catalog #				ration date planted, give date	
catalog # serial #			If im	planted, give date	
catalog # serial # lot #			If im		
catalog # serial # lot # other #			If im	planted, give date	
catalog # serial # lot # other # Device av <u>ail</u> able	for evaluati		If im	planted, give date	
catalog # serial # lot # other # Device available \[\sum_{yes} \sum_{no} \]	for evaluati	to m	If im	planted, give date	
catalog # serial # lot # other # Device av <u>ail</u> able	for evaluati	to m	If im	planted, give date	
catalog # serial # lot # other # Device available	for evaluati	to m	If im	planted, give date	
catalog # serial # lot # other # Device available	for evaluati Treturned dical produc	to m	If im	planted, give date	
catalog # serial # lot # other # Device available	for evaluati returned dical productions	to m	If implied in the state of the	planted, give date	
catalog # serial # lot # other # Device available yesno Concomitant me E. Reporter Name and addre The National Pe	for evaluati returned dical products ss diculosis A	to m cts	If implication	planted, give date	
catalog # serial # lot # other # Device available	for evaluating returned dical productions of the control of the co	p sssoo	If im If exp In exp If exp In exp If exp	planted, give date planted, give date urer /_ / (781)449-6487	
catalog # serial # lot # other # Device available	for evaluating returned dical productions of the control of the co	p sssoo	If im If exp In exp If exp In exp If exp	planted, give date planted, give date urer /_/ (781)449-6487	
catalog # serial # lot # other # Device available	for evaluation returned dical productions of the diculosis A dicul	p.ssociatio	If im If exp In exp If exp In exp If exp	planted, give date planted, give date urer /_/ (781)449-6487	

	_								
A. Patient I									
Patient Ider	ıtifier	Date of bi	irth	Sex	Weight				
	17	7-05-95		female	50	lbs			
B. Adverse	event	or produ	ict pr	oblem					
		Product	Prob	lem					
Outcomes at	ttribut	ted to adve	erse e	event					
\Box_{death}		\Box_{disab}	ility						
	☐ life-threatening ☐ congenital anomaly								
□hospitali	•			tervention					
other:		roqui							
Date of even	of 12-	29-99	Date	of report	1/11/2	2000			
Describe even			Dan	or report	1/11/2	2000			
After having		_	with N	Vix rid and	anell				
shampoos an		-			-				
bagging all st			_						
spray in my l			_						
Delevent tee	ta/lab	motour do	40						
Relevant tes	ts/iab(oratory da	ıa						
Other releva	ant his	story, incl	uding	g preexisti	ng condi	tion			
none									

Triage Unit Sequence #	

C. Suspect med	dication(s)				
Name: Kwell	alcation(3)				
	• 1				
nix and r	-				
Dose, frequency, route use The			rapy d	ates	
3oz on head for 20) minutes	12-2	24-99	to	
				01-11-2000	
Diagnosis for us	e		Event abated after use		
Head lice			stopped or dose reduced		
			no		
Lot #	Exp. date		Event	reappeared after	
	1			duction	
			Cinti	duction	
NDC# -	-		yes		
Concomitant me	dical produ	cts			
rid nix and baby o	=				
the baby oil suffo					
D. Suspect med	dical device				
Brand name					
Type of device					
Manufacturer na	ame and add	lress	Oper	ator of device	
				ealth professional	
				ser facility	
				istributor	
			_	ration date	
model #			Lipi	auton dute	
catalog #			If im	planted, give date	
serial #			-		
lot #			If ext	planted, give date	
other #				, , ,	
Device available	for evaluati	on?			
$\square_{\mathrm{yes}} \square_{\mathrm{no}}$	returned	to m	anufact	urer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and addre	SS	p	hone #	(781)449-6487	
The National Pe		ᆮ		(,61)	
P.O. Box 610189					
Health professio				Also reported to	
$\mathbf{V}_{\text{yes}} \square_{\text{no}}$	_	•		manufacturer	
If you do NOT wa	nt your identi	ty		user facility	
disclosed to the ma			an 🔲	distributor	

A. Buthad Life									
A. Patient Inform									
Patient Identifie	r Date of h	oirth Se	X	Weight					
14	08/02/91	fer	nale	50	lbs				
B. Adverse eve	nt or prod	uct prob	lem						
Adve	Adverse Event & Product Problem								
Outcomes attrib	uted to adv	erse even	ıt						
\Box_{death}	\Box_{disa}	bility							
□ life-threatenin	g \square_{cong}	genital ano	maly						
hospitalizatio		ired interv	-						
other:	1				ĺ				
	6/00	Date of	nonont	1/10/2	000				
		Date of	терогі	1/10/2	000				
Describe event o Treated with Nix a	=	out some	live lie	9					
immediately. Trea					ew				
live nymphs 3 day					. · · ·				
vominting									
Dolomont to stall al	4 J	-4							
Relevant tests/lal	ooratory a	ata							
Other relevant h	istory, inc	luding pr	eexisti	ng condit	ion				
asthma									

Triage Unit Sequence #	

C. Suspect medication(s)					
route use	Ther	apy da	ates		
One treat each drug,per pkg 1/5/			/5/00 to		
direction			1/6/00		
;	I	Event abated after use			
	s	stopped or dose reduced			
head lice					
Exp. date	Ī	Event 1	reappeared after		
	1	eintro	duction		
	\dashv	doesn'	t apply		
-					
ncal produ	cts				
ical device	<u>;</u>				
me and add	lress	Oper	ator of device		
		\square_{h}	ealth professional		
			ser facility		
		<u> </u>	istributor		
		<u> </u>	stributor		
		Expir	ration date		
		Expir			
		Expir If im	ration date		
		Expir If im	ration date		
for evaluati		Expir If im	ration date		
for evaluati	to ma	Expir If im _l If exp	planted, give date		
	to ma	Expir If im _l If exp	planted, give date		
returned	to ma	Expir If im _l If exp	planted, give date		
returned	to ma	Expir If im _l If exp	planted, give date		
returned	to ma	Expir If im _l If exp	planted, give date		
returned	to ma	Expir If imp If exp	planted, give date		
returned lical productions	to ma	Expir If imp If exp anufact	planted, give date		
returned lical productions ss diculosis A	phassoca	If implif expanufact	planted, give date planted, give date planted, give date urer _/_/ (781)449-6487		
returned lical productions s s diculosis A Newton, M	phassocation	If implif expanufact	planted, give date planted, give date planted, give date urer/_/ (781)449-6487		
	Exp. date	g,per pkg 1/5/0 I Exp. date I I I I I I I I I I I I I I I I I I I	Event a stopped yes Exp. date Event reintro doesn' lical products ical device me and address Operation		

A. Patient Inform	ation								
Patient Identifier	Date of birth	Sex	Weight						
9	3-2-88	female	80	lbs					
B. Adverse event	t or product p	roblem							
	Product Pro	blem							
Outcomes attribut	ted to adverse	event							
\Box_{death}	disability								
☐ life-threatening									
hospitalization	_	ntervention							
other: nit recur									
Date of event 9-22	2-99 Dat	e of report	1/7/2	2000					
Describe event or		e of report	1///2	.000					
Over 3 month perio	_	ear Stromeo	tol Ovide						
repeatedly along wi									
comb, Washing clot		_							
dryer, washing com				box					
springs& pillows in	plastic.								
Dalamant tagta/lab									
Relevant tests/labo	oratory data								
Other relevant his	story, includin	g preexisti	ng condit	tion					
Daily vacuumed car			pags and						
shoes and placed ov	ernight in cold	garage							

Triage Unit Sequence #	

C. Suspect medication(s)						
Name:						
see above description						
Dose, frequency, route use Therap				ates		
see above desscription 9-22			22-99			
			to 1-7-00			
Diagnosis for use			Event abated after use			
viewing nits			stopped or dose reduced			
vie wing mus			no			
Lot #	Exp. date					
Lot #	Ехр. часс			reappeared after oduction		
			remurc	duction		
NDC# -	-		doesn'	t apply		
Concomitant me	dical produ	cts				
D. Suspect med	dical device	е				
Brand name						
Type of device						
Manufacturer na	me and add	dres	Oper	ator of device		
			\square_{h}	ealth professional		
				ser facility		
			\Box_{d}	istributor		
			Expi	ration date		
model #						
catalog #			_ If im]	planted, give date		
serial #			-			
lot # other #			_ If exp	planted, give date		
	e 1 4					
Device available $\square_{\mathrm{yes}} \ \square_{\mathrm{no}}$	returned			turer / /		
Concomitant me			ianuraci	turer/_/		
E. Reporter						
Name and addre	SS	n	hone #	(781)449-6487		
The National Pe		ᆮ		(101)113 1101		
P.O. Box 610189, Newton, MA. 02461						
Health professional Occupation Also reported to						
$\mathbf{V}_{\mathrm{yes}} \square_{\mathrm{no}}$				manufacturer		
If you do NOT was	nt your ident	ity		user facility		
disclosed to the ma	ınufacturer, p	lace	an 🔲	□distributor		

A. Patient Inform	ation					
		G	TT7 . 1 . 1 . 4			
Patient Identifier 8	11-14-87	Sex female	Weight 70 lbs			
B. Adverse event			70 lbs			
b. Auverse even	Product Prob					
Outcomes attribut						
death	disability	event				
life-threatening	_	anomalı				
hospitalization		ntervention				
other:	— required ii	iter vention				
	0 D-4		1 /7 /2000			
Date of event 8-9		e of report	1/7/2000			
Describe event or	problem					
IICE						
Relevant tests/laboratory data						
Other relevant his	story, includin	g preexisti	ng condition			
noNE			J			

Triage Unit Sequence #	

C. Suspect medication(s)					
Name: Nix					
rid,LINDANE					
Dose, frequency,	route use	The	rapy da	ates	
IOTS		08/9	9		
				to 01/00	
Diagnosis for use	ρ		Event :	abated after use	
LICE	-		stopped or dose reduc		
LICE					
T 4 11	E 14			t apply	
Lot #	Exp. date			reappeared after	
			reintro	duction	
NDC# -			doesn'	t apply	
Concomitant med	dical prod	otc			
Concomitant med	aicai produ	cis			
D. Suspect med	lical device				
-	iicai device				
Brand name Type of device					
Manufacturer na	me and add	lress	Oper	ator of device	
			ı Â	ealth professional	
				ser facility	
			distributor		
			Expir	ation date	
model #					
catalog #		If im	planted, give date		
serial #					
lot #			_ If explanted, give date		
other #					
Device available					
	returned		anufact	urer//	
Concomitant me	dical produ	cts			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to					
$ \underline{v}_{\mathrm{yes}} \square_{\mathrm{no}} $)			manufacturer	
If you do NOT want your identity					
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor	

A. Patient Inform				
Patient Identifier	Date of birth	Sex	Weight	
5	1-17-91	female	70	lbs
B. Adverse event	or product p	roblem		
	Product Prol	olem		
Outcomes attribut	ted to adverse	event		
\Box_{death}	disability			
☐ life-threatening	□ congenital	anomaly		
□ hospitalization	required i	ntervention		
other:	-			
Date of event 8/99	9-1/00 Dat	e of report	1/6/2	2000
Describe event or		<u> </u>		
Reoccurring lice. N		npletely suc	ccessful.	
Going on all in all fo				
provided. Tried eve	erything - have	manually p	icked for	
countless hours.				
Relevant tests/labo	oratory data			
Other relevant his	story, includin	g preexisti	ng condi	tion
None	• ,		Ü	

Triage Unit Sequence #	

C. Suspect med	lication(s)					
Name: Nix						
Just not working no side effects yet						
Dose, frequency, route use Therapy dates						
Random		8/99				
				to 1/00		
Diagnosis for us	e		Event :	abated after use		
??				d or dose reduced		
			doesn'	t apply		
Lot#	Exp. date			reappeared after oduction		
NDC# -	-		doesn'	t apply		
Concomitant me	dical produ	cts				
Generic brands, ex	kact dates un	knov	vn			
D. Suspect med	lical device	•				
Brand name						
Type of device						
Manufacturer na	me and add	lress	Oper	ator of device		
			$\square_{\rm h}$	ealth professional		
			\square_{u}	ser facility		
			distributor			
			Expiration date			
model #						
catalog #			If implanted, give date			
serial #						
lot #			If explanted, give date			
other #						
Device available □ _{yes} □ _{no}				urer / /		
Concomitant me	dical produ	cts				
	,					
E. Reporter						
Name and address phone # (781)449-6487						
The National Pediculosis Association						
P.O. Box 610189, Newton, MA. 02461						
Health professional Occupation Also reported			Also reported to			
				manufacturer		
If you do NOT want your identity				user facility		
disclosed to the ma	nufacturer, p	lace	an 🔲	□distributor		

Patient Identifier 4 09/15/92 female 60 lbs B. Adverse event or product problem Adverse Event & Product Problem Outcomes attributed to adverse event death	A. Patient Inform	ation					
Adverse Event & Product Problem Outcomes attributed to adverse event death disability hospitalization required intervention other: Date of event 12/14/99 Date of report 1/6/2000 Describe event or problem Allergic skin reaction to Nix, required visit to PCP.	Patient Identifier	Date of b	irth	Sex	Weight		
Adverse Event & Product Problem Outcomes attributed to adverse event death	4	09/15/92		female	60	lbs	
Outcomes attributed to adverse event death	B. Adverse even	t or prod	uct p	roblem			
death disability life-threatening congenital anomaly hospitalization required intervention other: Date of event 12/14/99 Date of report 1/6/2000 Describe event or problem Allergic skin reaction to Nix, required visit to PCP.	Advers	se Event &	Prod	luct Proble	em		
life-threatening congenital anomaly hospitalization required intervention other: Date of event 12/14/99 Date of report 1/6/2000 Describe event or problem Allergic skin reaction to Nix, required visit to PCP.	Outcomes attribut	ted to adv	erse e	event			
hospitalization required intervention other: Date of event 12/14/99 Date of report 1/6/2000 Describe event or problem Allergic skin reaction to Nix, required visit to PCP. Relevant tests/laboratory data Other relevant history, including preexisting condition	death	disal	bility				
Other relevant history, including preexisting condition	life-threatening	\Box_{cong}	enital	anomaly			
Date of event 12/14/99 Date of report 1/6/2000 Describe event or problem Allergic skin reaction to Nix, required visit to PCP. Relevant tests/laboratory data Other relevant history, including preexisting condition	hospitalization	□requ	ired ir	ntervention			
Describe event or problem Allergic skin reaction to Nix, required visit to PCP. Relevant tests/laboratory data Other relevant history, including preexisting condition	other:						
Allergic skin reaction to Nix, required visit to PCP. Relevant tests/laboratory data Other relevant history, including preexisting condition	Date of event 12/	14/99	Date	of report	1/6/2	2000	
Relevant tests/laboratory data Other relevant history, including preexisting condition	Describe event or	problem					
Other relevant history, including preexisting condition	Allergic skin reaction	on to Nix,	requir	ed visit to I	PCP.		
Other relevant history, including preexisting condition							
Other relevant history, including preexisting condition							
Other relevant history, including preexisting condition							
Other relevant history, including preexisting condition							
Other relevant history, including preexisting condition							
Other relevant history, including preexisting condition							
Other relevant history, including preexisting condition							
Other relevant history, including preexisting condition							
Other relevant history, including preexisting condition							
Other relevant history, including preexisting condition							
Other relevant history, including preexisting condition							
	Relevant tests/laboratory data						
None		story, inc	luding	g preexisti	ng condi	tion	
	None						

Triage Unit Sequence #	

C. Suspect m	edication(s)				
Name: Nix					
Dose, frequency, route use The			erapy dates		
Ome treatment		12/10)/99	to	
				to 12/18/99	
Diagnosis for	use]	Event	abated after use	
Allergic reaction	n to Nix	s	stopped or dose reduce		
Ü			yes		
Lot #	Exp. date	_		1 6	
Lot "	Exp. date			reappeared after	
		ľ	reintroduction		
NDC# -	<u> </u>	\dashv	doesn'	t apply	
Concomitant n	nedical produc	cts			
None	F				
rvone					
D. Suspect m	edical device	,			
Brand name					
Type of device					
Manufacturer		lress	Oper	ator of device	
				ealth professional	
				ser facility	
			distributor		
			_		
			Expi	ration date	
model #			If im	planted, give date	
catalog #			11 1111	pianieu, give uate	
serial # lot #			TC .	.141	
other #			n exp	planted, give date	
Device availab	l. f				
yes \square_{no}			mufact	urer / /	
Concomitant n	nedical produ	cts	maract	<u> </u>	
	r				
E. Reporter					
Name and add	ress	ph	one #	(781)449-6487	
The National Pediculosis Association					
P.O. Box 6101	89, Newton, M	1 A. 0	2461		
Health profess	ional Occup	pation	n	Also reported to	
	no			manufacturer	
If you do NOT v	vant your identi	ity		user facility	
disclosed to the			ın 🔲	distributor	

A. Patient Inform	ation							
		G	TT7 1.4					
Patient Identifier 3	Date of birth 01-14-91	Sex female	Weight 75 lbs					
B. Adverse even			75 108					
b. Auverse even	Product Prob							
Outcomes attribut								
Outcomes attributed to adverse event								
	☐ death ☐ disability ☐ life-threatening ☐ congenital anomaly							
☐ life-threatening	_							
hospitalization other: treatmen		ntervention						
Date of event 12/9		e of report	1/5/2000					
Describe event or	problem							
treatment failure								
Relevant tests/labo	oratory data							
Other relevant his	story, including	g preexisti	ng condition					

Triage Unit Sequence #	

C Suspect mos	lication(s)				
C. Suspect medication(s)					
Name: lindane					
Dose, frequency,	route use	Thei	rapy d	ates	
normal treatment		11/99	9		
				to 1/00	
Diagnosis for us		l	Erront .		
Diagnosis for us	t		Event abated after use stopped or dose reduce		
lice			stoppe	u or dose reduced	
			no		
Lot#	Exp. date		Event	reappeared after	
				duction	
NDC# -	-	\Box	yes		
Concomitant me	dical produ	cts			
	arear produ				
D. Suspect med	lical device)			
Brand name					
Type of device			T		
Manufacturer na	me and add	lress	Oper	ator of device	
			\square_{h}	ealth professional	
			\square_{u}	ser facility	
			distributor		
				ration date	
madal #			LAPII	and and	
model			If im	planted, give date	
catalog # serial #				r	
lot #			If over	olanted, give date	
other #			III CA	manicu, give uale	
	C		<u> </u>		
Device available $\square_{\text{yes}} \square_{\text{no}}$	nor evaluati	ion?	£		
Concomitant me			anulaci	urer/_/	
Concomitant me	uicai produ	LIS			
E. Reporter					
Name and address phone # (781)449-6487					
The National Pediculosis Association					
P.O. Box 610189, Newton, MA. 02461					
Health professional Occupation Also reported to					
$\mathbf{\nabla}_{\mathrm{yes}}$ $\mathbf{\square}_{\mathrm{no}}$	1 -	, at 101	••	manufacturer	
If you do NOT want your identity user facility					
			,	distributor	
disclosed to the ma	muracturer, p	race a	111 🔳	ursurbutor	

A. Patient Info					
Patient Identifi			Sex	Weight	
2		20/49	female	130	lbs
B. Adverse eve	ent or p	product p	roblem		
		dverse Ev			
Outcomes attri	buted to		event		
death		disability			
life-threateni	ing \square	congenital	anomaly		
□hospitalizati	on \square	required in	ntervention		
other: 16 we	eks of n	niserable s	ymptoms		
Date of event 4	1/1998	Date	e of report	1/5/2	2000
Describe event	or prob	lem			
Used lindane as experienced seveskin that almost weeks. Nothing	ere anxie drove m helped.	ety, some d	izziness, ar	nd "prickly	y"
Reievant tests/i	aborato	ry data			
Other relevant No pre-existing i medication. I wa I followed the di	medical as a very	conditions healthy 4	. I was NC 8 year old v	T on any woman. A	And,

Triage Unit Sequence #	

C. Suspect m	edication	(s)				
Name: lindane	e					
Dose, frequen	cy, route u	se T	her	apy d	ates	
2oz bottle. App			/98			
12 hrs.			to 4/98			
Diagnosis for	use				abated after use	
Possible exposu	re to scabio	es.	S	toppe	d or dose reduced	
Precautionary of	only.			no		
Lot #	Exp. dat	e	_ I	Event 1	reappeared after	
				reintroduction doesn't apply		
NDC# -	<u>-</u>		\perp	uoesii	г арргу	
Concomitant n	nedical pro	oduct	s			
None. My ema	il is: taz_3	21@h	otn	nail.co	m	
D. Suspect m	edical de	vice				
Brand name						
Type of device						
Manufacturer	name and	addr	ess	Oper	ator of device	
				\square_{h}	ealth professional	
			user facility			
					istributor	
				<u></u>	ration date	
madal #				Lapii	ation date	
model # catalog #				If im	planted, give date	
serial #				1	, ,	
lot #				If ext	olanted, give date	
other #						
Device availab	le for eval	uatio	n?			
$\square_{\mathrm{yes}} \square_{\mathrm{nc}}$				<u>ınu</u> fact	urer//	
Concomitant r						
	_					
E. Reporter						
Name and add	ress		ph	one#	(781)449-6487	
The National	Pediculosi	s Ass	soci	iation		
P.O. Box 6101	00.37	n M/	A. 0	2461		
	89, Newtoi	1, 1117				
Health profess		ccupa		n	Also reported to	
Health profess ✓ yes		-		n	Also reported to manufacturer	
	ional Oo	ccupa	tio	n		

A. Patient Inform	ation			
Patient Identifier	Date of birth	Sex	Weight	
1	3-16-88	female	125	lbs
B. Adverse event	or product p	roblem		
	Adverse Ev	ent		
Outcomes attribut	ted to adverse	event		
death	disability			
☐ life-threatening	Congenital	anomaly		
hospitalization	☐required in	ntervention	1	
other: SEIZUR	Е			
Date of event 12-2	29-99 Date	e of repor	t 1/4/	2000
Describe event or		· · · · · · ·		
My 11 yr old had a headlice. She had a this has never happe	seizure days aft n eeg the next d	-		vet
Other relevant his My daughter has his taken Zoloft 75mg o	story, including	ı-typical aı		

Triage Unit Sequence #	