MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
387	11-13-95	female	37 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: Dr. visit

Date of event 09-15-00 | **Date of report** 9/18/2000

Describe event or problem

Infested with head lice in June 2000.Tried many over the counter shampoos without relief. Caused rash all over scalp. It became hard to tell if the scratching was from lice or rash. It was also hard to tell if it was nits or scabs.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
Rid, Clear, Brite-Life

Dose, frequency, route use
Used recommended dosages twice for each product

Therapy dates
06-2000 to 09-2000

Diagnosis for use
Kill head lice

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
381	3-26-96	female	31 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: rash along the neck

Date of event 9-5-00 **Date of report** 9/13/2000

Describe event or problem

daughters-head was itchy looked at her head noticed some lice, did not know what to do, called her doctor recommened nix used it next day, live louse and rash appeared.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
bottle of nix-used once

Therapy dates
9-5-00 to 9-13-00

Diagnosis for use
nixs, olive oil, rid spray

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

NDC # - -

Event reappeared after reintroduction
yes

Concomitant medical products

we have been using olive oil every night since we have out she had lice and i hope that this site can better inform me and my family wheter or not besides combing constantly

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
378	07-20-62	female	150 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: keep going to the doctors

Date of event 8-2-2000 **Date of report** 9/10/2000

Describe event or problem

Had scabbies. Was treated with Lyndane and 5 weeks later I am still iching to the point that I feel like I could loose my mind. I have bee to the doctors 4 times and they say it is a reaction to the cream that I applied.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I am till iching. Some one please help me.

C. Suspect medication(s)

Name: Kwell
Lyndane

Dose, frequency, route use
Only once

Therapy dates
8-5-2000 to 8-6-2000

Diagnosis for use
Lyndane

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
373	7-17-75	female	120 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: major skin irritation

Date of event 9-05-00 **Date of report** 9/7/2000

Describe event or problem

used the product Rid and it caused a major rash on my head, neck, ears, chest and shoulders had to miss work due to itching.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use

1

Therapy dates

9-05 to 9-05

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
363	10/24/94	male	48 lbs

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 8/8/00 **Date of report** 9/3/2000

Describe event or problem

Sibling infestation. Due to size of infestation (4 children) manual removal impractical.Used:
Rid,Nix,A200 - minimal kill. Adults alive.
Lindane - effective on live, <100% on eggs.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Had this happen during fall of 1999 also. Went through same course of treatment with the included attempts (at nurses recommendation) of a mayonaise treatment. With the exception of the Lindane, no treatment was effective.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
As per directions

Therapy dates
7/2900 to 8/11/00

Diagnosis for use
Control of lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
358	6/26/91	female	75 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: headaches

Date of event 10/99/ **Date of report** 9/2/2000

Describe event or problem

My daughter 1st got headlice 1yr.ago,I used rid,nix,& generic brands,nothing would kill the lice, after a couple treatments she started getting headaches. I've used the products about 10X with no luck,

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
Rid, generic brand

Dose, frequency, route use
about once a month

Therapy dates
8/99 to 8/00

Diagnosis for use
lice were never completely killed.

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
356	11-02-93	female	119 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: difficulty breathing -severe headache after treatm

Date of event 2-15-00 | **Date of report** 9/1/2000

Describe event or problem

daughter had severe headache and pain following use of head lice treatment, couldnt catch breath during use of treatment.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
directions on box

Therapy dates
2/18/00 to 2/19/00

Diagnosis for use
have no idea what you mean here

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
354	4/6/90	male	85 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: severe rash & sores

Date of event 11/95/ **Date of report** 8/31/2000

Describe event or problem

fall 95- large weeping blisters similar to chickenpox sore &product failure summer 00-product failure

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Nix
rid

Dose, frequency, route use
used according to labeled instructions

Therapy dates
11/95 to 12/95

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
353	10/16/95	female	62 lbs

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 08/20/00 **Date of report** 8/30/2000

Describe event or problem

have tried 2 separate products, each has failed to kill the lice

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
lindane

Dose, frequency, route use
once for the lindane, 2x with nix

Therapy dates
8/05/00 to 08/30/00

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
337	02/01/1995	female	55 lbs

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 07/22/2000 **Date of report** 8/23/2000

Describe event or problem

We have treated with Nix, Rid and lindane and after a month of treatments we still can not get rid of the lice.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Rid and Lindane prescription

Dose, frequency, route use

2 x a week rid or nix 1 x lindane

Therapy dates

07/22/00 to 08/22/00

Diagnosis for use

?

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

Should we use vinegar, olive oil, or any other treatments we heard will smother or help reduce the nits from sticking to hair?

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
336	01-18-93	female	60 lbs

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 6/26/8/21 **Date of report** 8/23/2000

Describe event or problem

they just keep reacurring and i have treated her 4xs already.i am scared to retreat any more.

i dont

again but i am afraid of doing somekind of damage to her.all the boxes say not to excede recommened doses.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Nix clear,lindane,and rid

Dose, frequency, route use

the recommended doses on the box for each label

Therapy dates

6/25/00 to 8/22/00

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

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** 8/22/2000

Describe event or problem

Nothing is working.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: lindane
Nix

Dose, frequency, route use
Lindane 2 weeks later Nix

Therapy dates
08/01/2000 to 08/18/2000

Diagnosis for use
Ineffective

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

Herbal shampoo.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
333	9/29/90	female	105 lbs

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 19/99/ **Date of report** 8/22/2000

Describe event or problem

Repeated treatment failure (Nix, Rid, Lindane, etc..) for head lice

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use

Every two weeks or so for the last year

Therapy dates

1999 to 9/2000

Diagnosis for use

Headlice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
328	09/23/00	female	21 lbs

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 7/26/00 **Date of report** 8/21/2000

Describe event or problem

Rid completely failed. Then we applied NIX. This also failed. Pediatrician prescribed Lindane. Appears to have worked. I wish I had known the side effects first. I would have lived with the bugs!!!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
rid and nix

Dose, frequency, route use
lindane used only once
rid used once and nix once

Therapy dates
7/26/00 to 8/1/00

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

NDC # - -

Event reappeared after reintroduction
yes

Concomitant medical products
rid 7/26/00 nix 7/28/00 lindane 8/1/00

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
325	9-28-1997	female	34 lbs

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 8-10-00 **Date of report** 8/19/2000

Describe event or problem

i applied kwell shampoo as instructed by both the doctor and pharmacist and still my child has lice

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

pharmacist said to use about an ounce

Therapy dates

8-10-00 to 8-17-00

Diagnosis for use

doctor diagnosed head lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

NDC # - -

Event reappeared after reintroduction

doesn't apply

Concomitant medical products

when 1st application failed to produce results i waited 1 week and then reapplied.still did not work

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
324	1-12-95	female	54 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: O.D. on chemicals

Date of event	Date of report
7/11/00	8/19/2000

Describe event or problem

My daughter was given Lindane for lice.It did not work,.I was told by the doctor to put 16oz. on her head leave it on for 10-15 min.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

actene,clear,nix,rid,equate

Dose, frequency, route use	Therapy dates
16oz.of LIndane,nix rid Clear,equate	7/11/00 to 8/12/00

Diagnosis for use

resistent head lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #	Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

sulfer antibiotic for infection on scalp.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
318	11/4/93	female	50 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: none

Date of event 8/11/00 | **Date of report** 8/16/2000

Describe event or problem

Found live lice and nits...treated with NIX and cleaned all bedding, bagged all non washables and vacuumed daily. Five days later still finding live lice daily and many nits. We check 2xs daily for them.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

day 4 developed 102* fever and vomited and exhausted..did the nix cause it or did she get the flu?

C. Suspect medication(s)

Name: Nix
permethrin 1%

Dose, frequency, route use
1/3 of 2oz bottle, once

Therapy dates
8/11 to 8/11

Diagnosis for use
nits and lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

NDC # - -

Event reappeared after reintroduction
doesn't apply

Concomitant medical products
picked her head daily 2 xs a day for bugs and nits.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
314	03-08-93	female	55 lbs

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 6/00 **Date of report** 8/13/2000

Describe event or problem

She has had head lice for about 2 months, I have tried every product including lindane.I comb and pick for hours daily but still cannot get rid of it.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name:

Numerous

Dose, frequency, route use

as directed

Therapy dates

6/00- to 8/00

Diagnosis for use

lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
312	00-00-1957	female	150 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: couldn't work

Date of event 08-11-00 **Date of report** 8/11/2000

Describe event or problem

used lindane and sprayed with RID and feel disoriented and eyes affected

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
RID spray

Dose, frequency, route use
twice

Therapy dates
07-00-00 to 08-11-00

Diagnosis for use
scabies

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
feeling much worse after spraying the RID

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
311	20-05-90	female	67 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☐ required intervention

other:

Date of event 8-08-00 **Date of report** 8/11/2000

Describe event or problem

Had grand mal seizure. Hartz 2 in 1 flea -- recommended by pharmacist. aunt shampooed her without knowing she had been treated 3 weeks before with NIX. RID spray was used at this time

Relevant tests/laboratory data

Other relevant history, including preexisting condition

she was perfectly normal before this. first encounter with head lice was 7 years ago and treated with lindane.

C. Suspect medication(s)

Name: Nix
RID spray

Dose, frequency, route use
1

Therapy dates
08-08-00 to 08-11-00

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

Now diagnosed as epileptic and had dilantin IV in ER and put on Depacote

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
310	6/95	female	53 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: extreme reddness to scalp(burning)

Date of event 8/95 **Date of report** 8/11/2000

Describe event or problem

The rid made my daughters scalp extemely red for two days to the point that she would cry if I even tryed to brush it. And the smell was just not tolerable.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid mayonaise

Dose, frequency, route use
Rid-once then mayonaise twice in a two day period.

Therapy dates
8/7/00 to 8/9/00

Diagnosis for use
neither worked!

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

8/10/00-We tried fully imersing hair in bath for 15min seemed to work well then we used the lice meister to get the rest of the lice out of her hair the water worked well we saw

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
307	10/13/1972	female	335 lbs

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 8/8/2000 **Date of report** 8/9/2000

Describe event or problem

Used nix ..... did not kill lice at all. Used lindane (the doctor prescribed it for me and my 3 yr old daughter) and it did not kill the lice.....

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
60 ml used once ...then repeated in 7 days

Therapy dates
8/1/00 to 8/8/00

Diagnosis for use
lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
302	8-28-95	female	39 lbs

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 7-23-00 **Date of report** 8/7/2000

Describe event or problem

WE STILL HAVE LICE. I THINK !!!????

Relevant tests/laboratory data

Other relevant history, including preexisting condition

NONE

C. Suspect medication(s)

Name: Nix
KWELL

Dose, frequency, route use
3-4 TIMES

Therapy dates
7-23-00 to 8-7-00

Diagnosis for use
TO GET RID OF LICE.

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
NONE

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
290	12/30/91	female	45 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 7/28/00	Date of report 7/30/2000

Describe event or problem

Each time (2) Lindane was used on our heads (Mother, sister, and child with lice), we all got sick 4-6 hours later with nausea and vomiting. this did subside by the next day. I am a nurse and used this product safely and according to the directions.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

No other preexisting medical conditions.

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use	Therapy dates
once a week for two weeks	7/11/00 to 7/28/00

Diagnosis for use	Event abated after use stopped or dose reduced
lice	yes

Lot #	Exp. date	Event reappeared after reintroduction
		yes

NDC # - -

Concomitant medical products

We used Nox to begin with ... no symptoms occurred, but the lice didn't go away.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address	Operator of device
	☐ health professional ☐ user facility ☐ distributor

	Expiration date
model # _____	
catalog # _____	**If implanted, give date**
serial # _____	
lot # _____	**If explanted, give date**
other # _____	

Device available for evaluation?
☐ yes ☐ no ☐ 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 reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
276	08-12-1987	female	200 lbs

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 02-2000 **Date of report** 7/22/2000

Describe event or problem

We have been trying to take care of lice since February. I'm an RN, I know how and what to do, nit picking, cleaning, repeat for newly hatched. I haven't gone to prescription products because I don't really want to use Lindane.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use
as stated on bottle

Therapy dates
02/2000 to 06/2000

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
I've also tried Nix and R&C.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
267	11/15/86	female	200 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: rash upon contact

Date of event 07/16/00 **Date of report** 7/18/2000

Describe event or problem

A Small amount was spilled upo9n this individual while another was being treated. A red rash and intense itching resulted when the product came into contact with the skin on her thigh the rash was almost instantaneous.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Rash lasted well over 3 hrs

C. Suspect medication(s)

Name: Rid

UNK

Dose, frequency, route use

Once

Therapy dates

071600 to 071600

Diagnosis for use

Head Lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

N/A

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
264	03-12-66	female	135 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: insanity!

Date of event 07/12/00 **Date of report** 7/12/2000

Describe event or problem

Exposed to head lice Memorial Day weekend. Used Nix twice, lindane twice, slept with olive oil for three weeks straight, combing for nits twice daily Huge hatch last Sunday night Do I ruin my career by shaving my head?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I am an insulin dependent diabetic.

C. Suspect medication(s)

Name:

lindane, Nix, elimite 5%, mayonaise, olive oil, pr

Dose, frequency, route use	Therapy dates
lindane 1% 2X Nix 1% 2X Olive Oil 20 days	06/02/00 to 07/12/00

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

I cannot get rid of this! Please help, my career and social life are being ruined! I fear I'm destroying my health, and my diabetes is totally out of control from all the stress.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
263	19/95/	female	42 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: bleeding head, sores

Date of event 6/17/00 **Date of report** 7/12/2000

Describe event or problem

lice I used Rid, my youngest started crying about 1 min. after i put it on. I washed it out asap.She is always rubing and pulling out her hair. Her I'm afaid to try anything on her head now.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

She has asthma..

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use

put on hair
had a screaming child.....

Therapy dates

7/17/00 to 7/17/00

Diagnosis for use

lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

none yet i don't know what to use..
I'm just combing her hair to get as many out as I can.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
256	3/4/92	female	60 lbs

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 5/00

Date of report 7/7/2000

Describe event or problem

Has been treated with Nix 4 times; Lindane once -- problem continues to exist. Going on 2 months now.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Asthma

C. Suspect medication(s)

Name: Nix

Lindane

Dose, frequency, route use

Nix - 4 times
Lindane - once

Therapy dates

5/00 to 7/6/00

Diagnosis for use

per bottle instructions

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
244	12/7/91	male	60 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☑ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☐ required intervention

other:

Date of event 1/16/00 | **Date of report** 7/5/2000

Describe event or problem

Grand Mall seizures. 3 events- 1/16/00, 5/4/00 and 7/2/00. All took place within 1 1/2 weeks of treatment with Nix. No previous history with seizures. Neurologist believes this shampoo is the reason.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None- perfectly healthy, great physical and mental shape. Never more than a cold in 8 years until this started this year.

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

1 time for each event. No follow up given

Therapy dates

1/5/00 to 7/1/00

Diagnosis for use

school epidemic

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

None

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
240	12-19-1992	female	65 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: Red/Burn scalp

Date of event 05-10-00 **Date of report** 6/30/2000

Describe event or problem

Used the "R.I.D." product on my children and my youngest suffered a very red and burned head,which was very painful to her, and still it didnt work?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

she has asthma,and is allergic to many things.

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

used it once to wash childrens heads with

Therapy dates

05-10-00 to 05-11-00

Diagnosis for use

To kill lice and nits on scalp.

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

Rid, Nix, Raid house bombs,2and 1 flea,lice and tick powder for carpets,Lice spray for bedding and upolstary.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
235	6/29/88	female	110 lbs

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.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

1 dose first week, 1 dose second week

Therapy dates

6/1/00 to 6/9/00

Diagnosis for use

?

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

We did the mayonaisse treatment and I found only 3 nits. I had found thousands the first day, and hundreds the next.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
234	08/21/75	male	165 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☑ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: terminal brain cancer

Date of event 10/01/1994 **Date of report** 6/25/2000

Describe event or problem

In a correctional facility he & inmates in 3 dormatories were instructed to leave lice treatment on OVERNIGHT. They experienced burning & peeling of the skin, allergic reactions, sores and scabs as a result.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Now, six years later, my son is dying of a malignant brain tumor.

My son was an otherwise perfectly healthy individual.

C. Suspect medication(s)

Name: lindane

Possibly Kwell

Dose, frequency, route use

They admitted mixing it wrong. Applied overnight.

Therapy dates

1/10/2000 to 6/26/2000

Diagnosis for use

Lice and/or scabies

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

Chemo wafers were implated in his brain at time of surgery and followed up with six weeks of radiation treatments.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
230	6-16-90	female	66 lbs

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 6-10-2000 **Date of report** 6/23/2000

Describe event or problem

lice still crawling after treatment

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix kwell

Dose, frequency, route use

been doing heads every 2 weeks for months

Therapy dates

2-2000 to 6-2000

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
226	01/19/90	female	100 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: non effective

Date of event 04/16/00 **Date of report** 6/18/2000

Describe event or problem

lindane is not effective for the treatment of head lice

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane 1%

Dose, frequency, route use
standard

Therapy dates
050500 to 061700

Diagnosis for use
lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
221	3/3/89	female	125 lbs

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 11-99 **Date of report** 6/12/2000

Describe event or problem

Have been trying unsuccessfully for 1 1/2 yr. Have tried every over-the-counter, lindane twice, even vaseline and mayo!! Affects both my girls ages 6 & 11 doesn't bother my son 4. Don't know what else to do.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name:

have tried everything

Dose, frequency, route use

****

Therapy dates

0-00 to 0-00

Diagnosis for use

****

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
218	07/22/88	female	83 lbs

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 02/00/ **Date of report** 6/9/2000

Describe event or problem

We used the following products and continued to find live lice:Nix,Rid, and Quell.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
Kwell,Rid

Dose, frequency, route use
unsure of dose,used each once

Therapy dates
02/00 to 06/00

Diagnosis for use
live lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
216	02/17/97	female	29 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: rash along nape of neck

Date of event 06/02/00 **Date of report** 6/4/2000

Describe event or problem

Used Nix to treat head & combed with nit comb.Next day child is still scratching & has a rash along the nape of her neck, I'm finding live lice in her head. I'm using the comb to try & find any eggs or lice daily.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
1 treatment & combed out with metal comb.

Therapy dates
06/01/00 to 06/01/00

Diagnosis for use
doctor advised to follow pckg directions.

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
215	03/05/65	male	11 lbs

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 24/05/00 **Date of report** 6/3/2000

Describe event or problem

HAVING TROUBLE GET RUD OF LICE FROM MY KIDS HEAD

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: malathion
AND ;LYCLEAR

Dose, frequency, route use
ABOUT THREE TIMES EACH ONE

Therapy dates
24/05/00 to 3/6/00

Diagnosis for use
N/A

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
no

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
212	03-16-95	female	45 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: broke out real bad

Date of event 05/00/ **Date of report** 5/29/2000

Describe event or problem

Used RID & it broke her out on the neck real big bumps & didn't kill lice,she had to go to Dr.for this also had a shot of antibiotic and got antibiotic cream.None of the med's. work for head lice even prescription all is very bad.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Asthma

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use

on hair for 10 min

Therapy dates

05/00 to 05/00

Diagnosis for use

lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

Nix April
Lindaine Shampoo March

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
208	10/07/87	female	124 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: loss of hair

Date of event	Date of report
06/96/	5/22/2000

Describe event or problem

after several uses hair started falling out by the hand full

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid

Mayo, Clear, Nix, Olive oil,

Dose, frequency, route use	Therapy dates
recommended dosage--used every ten days	06/96 to 05/00

Diagnosis for use

over the counter products

Event abated after use stopped or dose reduced

no

Lot #	Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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 reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
204	06/20/1990	female	118 lbs

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 03/20/00 **Date of report** 5/20/2000

Describe event or problem

I have used so many products. OTC and prescribed. Nothing works.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

My husband and youngest child have AB- blood I have A-. I have a friend whos husband also has AB- and he never gets them either. Could this be a factor...

C. Suspect medication(s)

Name: Nix

Rid, Lice Free, Pronto, Lindane

Dose, frequency, route use

As instructed

Therapy dates

03/2000 to 05/2000

Diagnosis for use

Lice infestation

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

06/1999

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
203	12-24-60	female	140 lbs

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 05-01-2000 **Date of report** 5/17/2000

Describe event or problem

Resistant head lice to Nix, Rid and Kwell shampoos. Trying olive oil and combing but still finding live lice. My daughter got lice from school in October. The nix shampoo helped her but mom got them .Would total coloring help?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
nix used several times

Therapy dates
3/1/2000 to 5/1/2000

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

NDC # - -

Event reappeared after reintroduction
no

Concomitant medical products

rid 3/1/2000 Kwell 2/1/2000 Olive oil treatments being used at present

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
198	4/17/89	female	56 lbs

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 19/93/ **Date of report** 5/14/2000

Describe event or problem

Recurrant head lice. Infestation spread to both parents (Male, DOB 5/7/1964 & Female DOB 1/13/1954).

Relevant tests/laboratory data

Other relevant history, including preexisting condition

From 1993 to the present, have seen numerous recurrances of head lice, including currant infestation which has lasted for over two years. I simply have given up. All three individuals have long or thick hair.

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

Used as directed on label and by doctor

Therapy dates

1995 to 1998

Diagnosis for use

Head lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

Nix, Rid, tea tree oil. Frequent use, over hter course of several years.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
197	12/10/93	female	52 lbs

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 5/12/00 **Date of report** 5/13/2000

Describe event or problem

Apparent resistance of head lice to Nix and permethrin 5%, resulting in prescription of lindane 1%.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
1 1/2 oz, 1st & 4th day

Therapy dates
5/5/00 to 5/12/00

Diagnosis for use
Massage thoroughly into scalp,

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

7th day, permethrin 5%, 20g, 8th day:lindane lotion1%, 1 oz.The lice are now gone. No mention was made of the dangers of lindane when prescribed by my doctor. I was

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
194	1/10/92	female	50 lbs

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	19/96/	Date of report	5/10/2000

Describe event or problem

I treated all three of my girls with Lindane lotion (Qwell) from the doctor and over the counter (Nix, generic, etc.) lice treatments only to have the lice return.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell
Nix, mayo, olive oil, lindane, pronto, sprays, etc

Dose, frequency, route use	Therapy dates
I followed container instructions	1996 to 2000

Diagnosis for use
Head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #	Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
192	11-30-00	female	48 lbs

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 05/04/00 **Date of report** 5/8/2000

Describe event or problem

04/24 treat with Rid
04/26/treat with Nix according to nurse-60 min
05/03 treat with Nix accd to pkg.
05/03 again accd to pkg
05/04 Dr. presc Lindane

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Rid
Nix 1%

Dose, frequency, route use
Rid once, Nix 3 times, Lindane once

Therapy dates
04/24/00 to 05/04/00

Diagnosis for use
Head lice that just wouldn't give up

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

No other medications or therapies were tried. I never would have guessed that the reason we couldn't get rid of them was because the lice are resistant. I am happy to say that at least

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
191	09-27-95	female	45 lbs

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 05-01-00 **Date of report** 5/8/2000

Describe event or problem

I have only described one child. (I have seven). I have done everything under the sun, including purchasing new bedding and perscription Lindane. Nothing works!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
all types of OTC shampoos

Dose, frequency, route use
typical dosage and frequency

Therapy dates
04-12-00 to 05-01-00

Diagnosis for use
Lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
189	06-13-88	female	120 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: complaints of headache and lethargic

Date of event 04-2000 **Date of report** 5/5/2000

Describe event or problem

complaints of haedache, fever and extreme lethargy after treatment of head lice (Lindane).

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Use of Nix x 3 with continuing outbreaks

C. Suspect medication(s)

Name: Nix
lindane

Dose, frequency, route use
Nix x 3 every 7 days
Lindane x 1

Therapy dates
04-03-00 to 05-05-00

Diagnosis for use
Nix/Lindane as directed

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
As described above

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association
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phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
188	01-08-1989	female	89 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: hair loss

Date of event 02/20/00 **Date of report** 5/2/2000

Describe event or problem

for the last 2 years my chrildren have been infested with head lice.
i have used everyting over the counter and every product,rx,and home remedy with no help.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
i have used almost every product on this list

Dose, frequency, route use
every 7 days

Therapy dates
08/99 to 05/00

Diagnosis for use
head lice infestion

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
as i have stated i have had no end to the lice i still remove manualy live lice and nits daily

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
158	18/05/83	female	130 lbs

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 04/00/

Date of report 4/19/2000

Describe event or problem

Two treatments with Derbac-M@ headlouse liquid, containing Malathion, failed to kill all lice. Live lice discovered after 6 days and a further 11 days. 3rd application being tried.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: malathion

Dose, frequency, route use

liberal application to scalp and hair

Therapy dates

2/04/00 to 19/04/00

Diagnosis for use

visible lice and nits

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
157	01/15/1962	female	135 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: keeps comming back

Date of event 04/28/2000 **Date of report** 4/29/2000

Describe event or problem

this has been an on going problem for about 3 years. we also have been using (alpharma) as a shampoo.and a flea comb.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
kwell

Dose, frequency, route use
shampo 3 times a month and about 9 mo a year

Therapy dates
1997 to 2000

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

NDC # - -

Event reappeared after reintroduction
yes

Concomitant medical products
Rid to spray the house for 3 years7/1/97to 4/29/2000

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
154	11/26/2000	male	49 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: Flu symptoms

Date of event 4/16/00 | **Date of report** 4/22/2000

Describe event or problem

Treated with NIX Creme Rinse evening of April 14. Morning of April 16 my son had a fever of 39C. Vomiting started and lasted until the following day at noon. Inflamed tonsils, he could hardly swallow and ended up with a very bad ear infection.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

My son had head lice about two years ago and after treatment he had the same flu symptons as this time.

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

One application, left on for ten minutes.

Therapy dates

4/14/00 to 4/14/00

Diagnosis for use

1 appl. left on for 10 min.

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

Lice reappeared after one week. I am treating with Olive Oil left on for three hours. I am NOT covering head with shower cap or plastic. April 22,2000.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
152	2-7-98	female	24 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: reoccuring lice; 5 times now in just a couple of m

Date of event 4/16/00 **Date of report** 4/17/2000

Describe event or problem

Alexexandra(2),Erinn(8, and Jacquie(41)years old. All have had head lice 5 times in the past 2-3 months. After 1 Rid and 4 NIX treatments, professionally cleaned carpet, furniture, hair cuts and repeated clothing cleanings.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Alex(2) has Cornelia De Lange Syndrome. She has been treated for the lice all five times with NIX or Rid and hasn't showed any signs of adverse reaction,except for sleeplessness and awaking as if in pain (a Cornelia De Lange occurrence) Jacquie(41) and E

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
5 times on all 3 people over the past 2 months

Therapy dates
2/20 to 4/15

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

NDC # - -

Event reappeared after reintroduction
yes

Concomitant medical products

Rid was used first in February, but we changed to NIX per recommendation of a physician for the other 4 treatments

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
151	19/87/	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:

Date of event 20/00/ **Date of report** 4/14/2000

Describe event or problem

Product failure

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: malathion

Hair lice shampoo;permethrin,piperonyl,excipients

Dose, frequency, route use

Shampoo 300ml
Malathion (0.5% malathion)

Therapy dates

15/02 to 13/04

Diagnosis for use

Head Lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
149	11/19/92	female	58 lbs

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 3/00

Date of report 4/11/2000

Describe event or problem

We used Nix twice, mayonaise treatment once, and Lindane, and still did not get rid of the lice.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
lindane, and mayonaise

Dose, frequency, route use
Nix two times, mayonaise once, Lindane once

Therapy dates
3/10 to 4/10

Diagnosis for use
did not kill lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
147	09-23-91	female	50 lbs

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 04-04-00 **Date of report** 4/7/2000

Describe event or problem

product failure

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
nix

Dose, frequency, route use
once every two weeks

Therapy dates
03-00 to 04-05-00

Diagnosis for use
headlice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
146	01/24/96	male	48 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☑ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☑ required intervention

other:

Date of event 01/24/96 **Date of report** 4/5/2000

Describe event or problem

born with bronchogenic cyst,required major lung surgery to right lung. since treated for asthma. also has been diagnosed with strabissmus,requires corrective lenses to prevent further crossing of eyes.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
once

Therapy dates
1995 to 1995

Diagnosis for use
mother had genital lice while pregnant with alec

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
142	08-16-1992	female	48 lbs

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 03-15-00 **Date of report** 4/2/2000

Describe event or problem

Kids got it. Treated w/Nix 3times in one week. Vacuumed, sprayed, bagged toys, etc., won't go away.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
Nix

Dose, frequency, route use
1 bottle Nix
3 x wk

Therapy dates
3-15-00 to 4-1-00

Diagnosis for use
no instructions

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Lindane - eight months ago, Nix several times

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
141	02/13/89	female	89 lbs

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 02/01/2000 **Date of report** 4/1/2000

Describe event or problem

We have tried since December of 1999 nothing is working we have spent about 700 dollars we have had

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Nix

Rid, kwell, Nemph oil

Dose, frequency, route use

one bottle family size per person

Therapy dates

12/01/99 to 04/01/2000

Diagnosis for use

HEAD LICE

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
138	7-3-1991	female	75 lbs

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 3-23-2000 **Date of report** 3/30/2000

Describe event or problem

after treating with nix and using the comb provided i waited a couple of days and checked her again, i found live adult lice. and still numorous nits, the comb does not remove the nits very well. is there something else i can try?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
used twice within a four day period,

Therapy dates
3-23-2000 to 3-29-2000

Diagnosis for use
found head lice and nits in childs hair,

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
135	05/24/71	female	128 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: premature labor and diagnsed with cyst on brain

Date of event 7/95

Date of report 3/29/2000

Describe event or problem

had genital lice, given lindane shampoo by e.r. doctor

Relevant tests/laboratory data

Other relevant history, including preexisting condition

app.3 months/4 months pregnant

C. Suspect medication(s)

Name: lindane
came wit no label

Dose, frequency, route use
used once

Therapy dates
7/95 to 7/95

Diagnosis for use
genital lice

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
no

NDC # - -

Concomitant medical products
none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
131	8/22/75	male	185 lbs

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 06/20/2000 **Date of report** 3/21/2000

Describe event or problem

both lindane, used 4 times total, in two sep.treatment episodes, and elimite, used in same manner, failed to erradicate scabies, all necessary precautions were taken and product was used correctly-suspect resistant scabies

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
elimite

Dose, frequency, route use
one treatment followed by another 7 days later

Therapy dates
6/99 to 2/00

Diagnosis for use
scabies

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
eucalyptus oil/ tea tree oil

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
130	04/22/95	female	42 lbs

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 03/13/00 **Date of report** 3/20/2000

Describe event or problem

I TREATED HER MONDAY NIGHT, TWICE ON TUESDAYAND TWICE ON WEDNESDAY. ON SUNDAY I BOUGHT SOME LINDANE AND TREATED HER WITH THAT. STILL FOUND LIVE LICE

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

kwell, RID

Dose, frequency, route use

1X MON,2 X TUES, 2X WED 1X SUN

Therapy dates

03/13/00 to 03/19/00

Diagnosis for use

ITCHING, RED NECK, WHITE EGGS IN HAIR

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

I THINK SHE HAS HAD PLENTY OF EXPOSURE

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
125	10-23-62	female	140 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other: SIDE EFFECTS

Date of event 02-14-00 **Date of report** 3/15/2000

Describe event or problem

BROKE OUT ON HANDS ARMS SHOULDERS,& BELTLINE, JUST AFTER MY 7 YR OLD DAUGHTER CONTRACTED & I DID HER TREATMENT FOR HEAD LICE USING RID

Relevant tests/laboratory data

Other relevant history, including preexisting condition

PSORISIS, SINCE THE AGE OF 20, NOW APPEARS TO BE CLEARING UP FOLLOWING TRIAMCINOLONE .1% CREAM TREATMENT, HOWEVER,STILL DON'T SEEM 100% CURED

C. Suspect medication(s)

Name: lindane .1%, LOTION & SHAMPOO

Dose, frequency, route use

2 OZS HEAD TO TOE, REPEATED SAME 10 DAYS FOLLOWING

Therapy dates

02-14-00 to 3-14-00

Diagnosis for use

SCABIES

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

TRIAMCINOLONE .1% CREAM

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
116	02/05/97	female	38 lbs

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 8/99-3/00 **Date of report** 3/7/2000

Describe event or problem

Resistace to Rid, Nix, Kwell, and Scabie prescription

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid
Nix

Dose, frequency, route use
Rid & Kwell once Nix & prescription three times

Therapy dates
8/99 to 3/00

Diagnosis for use
didn't work

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
114	11-24-85	female	125 lbs

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 08-06-99 **Date of report** 3/3/2000

Describe event or problem

No products work on killing lice in my hair i've tried Ladine about 3 times and almost everything else on the shelf.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
3 times

Therapy dates
08-06-99 to 01-01-00

Diagnosis for use
Lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
111	03/13/89	female	82 lbs

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 02/26/00 **Date of report** 3/1/2000

Describe event or problem

Nix and Lindane failed to kill lice.We have and continue to remove nits but have had trouble finding lice. We have seen only small amounts of lice on our daughter but are dismayed to find any after such agressive treatment. Please help if you can

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
One bottle???once

Therapy dates
02/27/00 to 02/27/00

Diagnosis for use
Nits in hair

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
Nix was used 02/26/00 once one bottle 2 oz.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
108	2/22/77	female	135 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: infestation worsened bumps on head and sores

Date of event 2/27/00 | **Date of report** 2/28/2000

Describe event or problem

I have bumps and sores on my head as well as a serious increase in infestation rather than a decrease

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Clear

Dose, frequency, route use	Therapy dates
2oz. 10 days ago	2/17/00 to 2/27/00

Diagnosis for use

two oz & removal cream repeat

Event abated after use stopped or dose reduced

no

Lot #	Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

previos infestation over a year

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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 reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
105	05/12/88	female	90 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: none of the above

Date of event 12/99-2/00 **Date of report** 2/24/2000

Describe event or problem

We have used NIX, RID, olive oil, tea tree and the prescription Lindane. Nothing has worked for us. We have cleaned with Lysol,RID spray and sealed the bedding with plastic covers. I am at my wits end.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None she is the healthest child I have. Minor ear infections, no major problems. No hospitalizations.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
2 times

Therapy dates
12/99 to 02/00

Diagnosis for use
2 oz

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

We used RID AGAIN tonight and I will take her to the doctor if it reoccurs again.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
103	6-13-88	female	155 lbs

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 2-17-00 **Date of report** 2/21/2000

Describe event or problem

Step Daughter has headlice.Many, many nits. Applied Nix rinse to hair, left on for 10 mins. as instructed. Picked hair for 4-1/2 hrs. Next morning, found 12 live louse and still finding more.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Step-daughter had outbreak of headlice the first week in January, not sure how long she had had it prior to this time. She lives with her biological mother. Mother talked to ER Dr. and was issued a perscription for Lindane shampoo. We were told that it wa

C. Suspect medication(s)

Name: lindane

Also NIX

Dose, frequency, route use

shampoo @ 5 day intervals
Nix: 1 application

Therapy dates

1-8-00 to 2-17-00

Diagnosis for use

Head Lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
102	06/25/90	female	85 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: headaches

Date of event 02/15/00 | **Date of report** 2/20/2000

Describe event or problem

after second treatment with Nix, a couple days later now she is complaining of headaches

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

one 3fl. ounce bottle every week for two weekends

Therapy dates

02/03/00 to 02/13/00

Diagnosis for use

lice and nits

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
101	05/02/1999	female	13 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 08/15/1999 **Date of report** 2/20/2000

Describe event or problem

Allergic response, inconsolable crying, rash, hives, swelling

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name:

Elimite

Dose, frequency, route use

one treatment per ea.attempt

Therapy dates

08/15/1999 to 08/15/1999

Diagnosis for use

scabies

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

none; benadryl given after reaction. Scabies symptoms still continue today, 02/18/2000

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
98	1/19/86	female	124 lbs

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 20/00/ **Date of report** 2/18/2000

Describe event or problem

none of the shampoos including Lindane, Nix or the generics are not working. Live bugs are still present even after leaving on for a prolonged time.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: generic lice shampoo
lindane

Dose, frequency, route use
once a week, sometimes every 2 weeks

Therapy dates
1999 to 2000

Diagnosis for use
I'm not sure

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
94	6/94	female	65 lbs

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 7/99

Date of report 2/15/2000

Describe event or problem

chronic lice head infestation over the last six months. Has not been clear of live lice and nits.treated with multiple of pediculicides and suffocating treatments.6 other children in this home have not had lice please help!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Clear

kwell, Nix, Rid

Dose, frequency, route use

1 time per per or more

Therapy dates

7/98 to 2/00

Diagnosis for use

live head lice and nits

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

vaseline, mayionase, quene Helene,

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
89	07/07/92	female	45 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: Scalp Dermatitis

Date of event 02/01/2000 **Date of report** 2/12/2000

Describe event or problem

Constant treatment for recurring head lice from school. School will not remove children with head lice so our child keeps getting reinvested. We have pulled Brittany out of school and will not send her back untill school can gaurantee no head lice.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
R & C

Dose, frequency, route use
Weekly as described on the product label.

Therapy dates
11/03/99 to 02/10/2000

Diagnosis for use
Caused scalp iritation and soreness.

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Olive oil

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
88	0-00-92	female	72 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: doctor confirmed adverse

Date of event 2-10-00 **Date of report** 2/11/2000

Describe event or problem

She was skating yesterday and got a muscle spasm in her neck -- headache and stomach ache -- this is all after many NIX treatments. Doctor saw her and said extremely swollen glands. Put her on Motrin for pain.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

General health okay with normal flu and colds. Doctor gave her the Motrin. WE have sprayed with the NIX spray quite a bit in the beginning since September and October.

C. Suspect medication(s)

Name: Nix
Nix spray at the same time

Dose, frequency, route use
many times

Therapy dates
9-00-99 to 2-10-00

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

motrin for pain associated with this event prescribed by doctor

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
87	11-17-75	female	172 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: death in unborn child

Date of event 11-9-99 | **Date of report** 2/10/2000

Describe event or problem

was using lice treatments while pregnant, find out that there were many defects that just don't happen together.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

RID, NIX, generic brands, and sprays

Dose, frequency, route use

used atleast 2 times a month

Therapy dates

6-98 to 10-99

Diagnosis for use

stepdaughter had lice, was using as cure

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
83	1/26/93	female	69 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: sores on head from treatment

Date of event 1/2000 **Date of report** 2/7/2000

Describe event or problem

got nix and used it and she returned to school but was sent home 2 days later with them again, removed nits and sent back to school, retreated 7 days later. she has sores on her head from the treatment

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
2 bottles 7 days apart

Therapy dates
1/2000 to 1/2000

Diagnosis for use
school found them

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

have used cream rinses left on hair over night because of the sores on her head, this is a daily thing since if we do not do this we find lice on her scalp

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
80	09/24/85	female	105 lbs

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 01/01/98 **Date of report** 2/3/2000

Describe event or problem

have been trying for over one year to get rid of these pests. Both my daughter and myself have had an ongoing problem.The licemeister comb helps but within a week of stopping daily combings with it we both have nits. My husband has not been infested.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

nix, olive oil, tea tree oil

Dose, frequency, route use

multiple

Therapy dates

01-01-98 to 02/04/00

Diagnosis for use

head lice infestation

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

multiple

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
78	19/83/	female	170 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: boils on scalp

Date of event 1-2000 | **Date of report** 2/2/2000

Describe event or problem

have 2 childten, have treated both children at least 5 times this school year completely removed all nits, cleaned entire house, left house for two days, after school breaks and they go back to school with in two weeks they have lice again.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: tea tree oil
mayonaise, rid, nix, olive oil,clear

Dose, frequency, route use
every 7 to 10 days each time

Therapy dates
8/1999 to 1/2000

Diagnosis for use
lice removal

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
76	02/02/90	female	65 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: Hives

Date of event 01/28/00 **Date of report** 2/2/2000

Describe event or problem

My daughter broke out in hives (an itchy rash) on her scalp, neck and shoulders. Needless to say, none of the treatments affected the lice

Relevant tests/laboratory data

Other relevant history, including preexisting condition

No pre existing medical conditions

C. Suspect medication(s)

Name:

All OTC shamppos and sprays, also Lindane

Dose, frequency, route use

As directed on the labels

Therapy dates

09-99 to 02/02/00

Diagnosis for use

?

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

Often this school year, average of once to twice a month

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
55	9-30-92	female	65 lbs

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 1999-2000 **Date of report** 1/25/2000

Describe event or problem

The school sent home a note saying to check the kids heads for lice.I have tried everything.the schools did not check the childrens hair.I have tried Rid, Nix, Clear and store brands of treatments..they just keep coming back.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Clear
Kwell, Nix, Mayonnaise, Rid, store brands

Dose, frequency, route use
once every 7-10 days as directed

Therapy dates
1999 to 2000

Diagnosis for use
no help

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
54	3/21/91	female	64 lbs

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 1/24/00 | **Date of report** 1/24/2000

Describe event or problem

the products simply do not work

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

Followed prescription directions, used 3times

Therapy dates

12/20/99 to 1/24/99

Diagnosis for use

to kill headlice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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The National Pediculosis Association

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
53	7/8/92	female	48 lbs

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 8/99-1/00 **Date of report** 1/24/2000

Describe event or problem

Head lice I CANNOT get rid of!! My daughter got it on a family beach trip in late August and I have not been able to rid her of them since! I have done EVERYTHING physically possible!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name:

...Kwell, Nix, Mayo, tea tree oil, now this totalh

Dose, frequency, route use

as indicated since initial outbreak

Therapy dates

8/25/99 to 1/21/2000

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
52	9/26/65	female	145 lbs

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 1/99

Date of report 1/24/2000

Describe event or problem

All of my children have been having headlice for what seems like forever' we have tried every single different type of lice treatment that is found in Wal-Mart and in K-Mart and drug store. I just do not know what else to do.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix Rid, kwell Rite Aid

Dose, frequency, route use

Every two weeks for over 3 months

Therapy dates

8/99 to 1/00

Diagnosis for use

headlice, 7 children mom and dad

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

I don't know the dates..

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
23	12/10/93	female	40 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☐ required intervention

other:

Date of event 11/98/

Date of report 1/15/2000

Describe event or problem

Severe burns on the scalp and recurring infestations

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: generic pyrethrin

rid and Nix have been used also

Dose, frequency, route use

Two shampoos

Therapy dates

11/98 to 1/00

Diagnosis for use

Removal of head lice with a nit removing comb

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
22	10/11/90	female	90 lbs

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 01/14/00 **Date of report** 1/15/2000

Describe event or problem

this is her 7th year in the public school system, we have never had a problem until this year. has had head lice 5 times: We have used all the treatments, Rid, Clear, etc I am going to cut her hair shorter and try the tea oil shampoo and oil extract

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Clear

kwell, rid, generic

Dose, frequency, route use

every 4-7 days

Therapy dates

110199 to 011400

Diagnosis for use

lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
18	05-03-93	male	52 lbs

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 12/22/99 **Date of report** 1/11/2000

Describe event or problem

Our son was treated 3 times with Nix then twice with lindane .

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
lindane

Dose, frequency, route use
5 treatments in 3 weeks

Therapy dates
12/22/99 to 1/10/00

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

NDC # - -

Event reappeared after reintroduction
yes

Concomitant medical products

Rinsed with 5o/50 vinegar and water solution prior to applying lindane.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
17	7-05-95	female	50 lbs

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 12-29-99 **Date of report** 1/11/2000

Describe event or problem

After having treated my child with Nix rid and quell shampoos and throwing away all pillows, brushes and bagging all stuffed animals and using 6 cans of bedding spray in my home, my child was still infested

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Kwell

nix and rid

Dose, frequency, route use

3oz on head for 20 minutes

Therapy dates

12-24-99 to 01-11-2000

Diagnosis for use

Head lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

rid nix and baby oil

the baby oil suffocated the lice

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
14	08/02/91	female	50 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 1/6/00

Date of report 1/10/2000

Describe event or problem

Treated with Nix and combed out some live lice immediately. Treat with Pronto. Continuing to recover few live nymphs 3 days later. Treatments caused nausea / vominting

Relevant tests/laboratory data

Other relevant history, including preexisting condition

asthma

C. Suspect medication(s)

Name: Nix
Pronto

Dose, frequency, route use

One treat each drug,per pkg direction

Therapy dates

1/5/00 to 1/6/00

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
9	3-2-88	female	80 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: nit recurrence

Date of event 9-22-99 **Date of report** 1/7/2000

Describe event or problem

Over 3 month period used Nix, Clear, Stromectol, Ovide repeatedly along with DAILY "Nit Picking", electronic comb, Washing clothing,bedding, coats in hot water/hot dryer, washing combs and brushes, covering mattresses, box springs& pillows in plastic.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Daily vacuumed car and house, sprayed book bags and shoes and placed overnight in cold garage

C. Suspect medication(s)

Name:

see above description

Dose, frequency, route use

see above desscription

Therapy dates

9-22-99 to 1-7-00

Diagnosis for use

viewing nits

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
8	11-14-87	female	70 lbs

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 8-99 **Date of report** 1/7/2000

Describe event or problem

lICE

Relevant tests/laboratory data

Other relevant history, including preexisting condition

noNE

C. Suspect medication(s)

Name: Nix rid,LINDANE

Dose, frequency, route use

lOTS

Therapy dates

08/99 to 01/00

Diagnosis for use

LICE

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
5	1-17-91	female	70 lbs

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 8/99-1/00 **Date of report** 1/6/2000

Describe event or problem

Reoccurring lice. No treatment completely successful. Going on all in all for 4 months. More details can be provided. Tried everything - have manually picked for countless hours.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: Nix

Just not working no side effects yet

Dose, frequency, route use

Random

Therapy dates

8/99 to 1/00

Diagnosis for use

??

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

Generic brands, exact dates unknown

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
4	09/15/92	female	60 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ 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.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

Ome treatment

Therapy dates

12/10/99 to 12/18/99

Diagnosis for use

Allergic reaction to Nix

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

None

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
3	01-14-91	female	75 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: treatment failure

Date of event	12/99/	Date of report	1/5/2000

Describe event or problem
treatment failure

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use	Therapy dates
normal treatment	11/99 to 1/00

Diagnosis for use	Event abated after use stopped or dose reduced
lice	no

Lot #	Exp. date	Event reappeared after reintroduction
		yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ 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 reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
2	11/20/49	female	130 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: 16 weeks of miserable symptoms

Date of event 4/1998 **Date of report** 1/5/2000

Describe event or problem

Used lindane as proventative when my child had scabies. I experienced severe anxiety, some dizziness, and "prickly" skin that almost drove me to suicide. Symptoms lasted 16 weeks. Nothing helped.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

No pre-existing medical conditions. I was NOT on any medication. I was a very healthy 48 year old woman. And, I followed the directions given me by the doctor EXACTLY.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
2oz bottle. Applied once for 12 hrs.

Therapy dates
4/98 to 4/98

Diagnosis for use
Possible exposure to scabies. Precautionary only.

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
None. My email is: taz_321@hotmail.com

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
1	3-16-88	female	125 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: SEIZURE

Date of event 12-29-99 **Date of report** 1/4/2000

Describe event or problem

My 11 yr old had a seizure days after using NIX for headlice. She had an eeg the next day - it was normal- yet this has never happened before.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

My daughter has high functioning a-typical autism and has taken Zoloft 75mg daily for three years.

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

1 time for 15 minutes

Therapy dates

12-23-99 to 1/2/00

Diagnosis for use

headlice

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

Other therapy date will be January 11 for evaluation. I'll let you know.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ 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

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐