MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
1435	05/04/1950	male	160 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 04/20/04 **Date of report** 1/26/2005

Describe event or problem

In April of 2004 I became infested with lice from a visit to the hospital.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I've got itchy "crawly-feeling" scalp. I have NOT been able to locate any actual lice and nits; however, I wash out a number of "questionable" things out of my hair on a regular basis.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

5%

Therapy dates

04/2004 to 01/2005

Diagnosis for use

Prescription was for two (2) uses/treatments.

Event abated after use stopped or dose reduced

no

Lot #

Anti-biotics

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

Ive tried mayonaise, over-the-counter shampoos, "internet-ordered" shampoos/treatments, essential oils, etc. I have quite a collection of lice and nit removal combs whick I have

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
1432	03/16/00	female	33 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 01/17/05 **Date of report** 1/22/2005

Describe event or problem

While using the peditrician prescribed Ovid my 4 year old has a sever scalp reaction. She screamed for 40+ min while we tried to neutralize the medication. Lice were not effictively killed as a resullt of not being able to keep the $106.00 prescription on her tiny head. The Drs office said they used this on children as young as 2. I find this hard to believe. This has been a terrible battle.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: malathion

Dose, frequency, route use
one time for less than 1 hour

Therapy dates
01/17/05 to 01/17/05

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
Nix - also caused less severe irritation and itching

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
1430	11-27-58	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: paychological trauma and loss of wages over a lo

Date of event 10/03/ **Date of report** 1/18/2005

Describe event or problem

My family was exposed to head lice at their public school and all three of them brought it home. It spread to myself, my daughter's grandmother and our friend's two children. Each of those individuals had a case of it twice after which we have had no furter contact with them. It also spread to several of my children's classmates at the YMCA gymnastics. We were asked to leave the programs at the YMCA per-manently. My oldest daughter is a gymnast and cannot continue her career unless I enroll them at much more expensive academy. A local social service agency has threatened a dependency hearing for the girls based on their missing weeks of school. A meeting is being held with them and the local school officials,myself and several other members of the community. I have retained a lawyer to advise me of my rights as I feel they have already been

Relevant tests/laboratory data

Other relevant history, including preexisting condition

We have been using the treatments prescribed by our family physicians over and over and they have caused pain in the scalp and behavioral changes in my daughter such as severe acting out,temper tantrums and severe, uncontollable anger.

C. Suspect medication(s)

Name: Nix

Ovide,lindane,Rid, mayonaise

Dose, frequency, route use

1 bottle per family member, once per week

Therapy dates

10-2004 to 1-2005

Diagnosis for use

pediculosis

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

all medications used frequently over the 2 and a half year period since the inception of this infection

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
1416	11/13/89	female	136 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: intense itching

Date of event 11/24/2004 **Date of report** 12/22/2004

Describe event or problem

We have been treating headlice for over a year going between lice shampoos and strictly combing. After treating her with the shampoo she started itching all over and broke out in a rash on her stomach, legs, and bottom. Although the rash stayed there her skin itches. When I took her to the dr. , he took one look and said scabies, no tests were done to make sure. He said the treatment would be the same for any results. Not happy. did the on going headlice problem cause the scabies. I have 5 other children and only the youngest two (4years old) seem to catch headlice and keep it. Need Help!!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

The child with scabies, 15years old, has bronchial asthma (mild) and is allergic to erythromiacin. The twin 4 year olds have no preextisting medical conditions.

C. Suspect medication(s)

Name: generic lice shampoo

Dose, frequency, route use

use entire bottle. thick hair. no more than once a month.

Therapy dates

11/24/04 to 12/21/04

Diagnosis for use

once headlice.

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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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
1413	03/30/1966	female	150 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: Hodgkin's Disease-cancer

Date of event 1993-1994 **Date of report** 12/15/2004

Describe event or problem

We used Kwell as kids and it had to remain on for hours it seems. All of us developed some sort of lymph node condition.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

nothing regular, just shampoo it on and leave it there about an hour

Therapy dates

1978 to 1980

Diagnosis for use

Lice on head of foster child living with family.

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

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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
1411	07/11/2000	male	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:

Date of event 12/10/04	Date of report 12/13/2004

Describe event or problem

TREATMENT FAILED

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
1%

Dose, frequency, route use	Therapy dates
ONCE	12/10/04 to 12/10/04

Diagnosis for use
SCABIES TREATMENT...3 TREATMENTS OF ELIMITE

Event abated after use stopped or dose reduced
yes

Lot #	Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
ELIMITE NOV 21ST UNTIL 12/08/04 UNSUCCESSFUL

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	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
1406	03/02/91	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: continued reinfestation of lice

Date of event 11/12/04 **Date of report** 11/16/2004

Describe event or problem

After treating my daughter with Nix for the third time in six weeks, I found live, crawling lice--dozens of them--on her head the very next morning. (I used a battery-powered Robi-comb, which is the only thing I'll ever use again!) That is when I realized that all the previous treatments must also have failed, allowing the lice to reproduce and multiply with abandon. This, despite having spent hours and days washing, drying, bagging, vacuuming and nitpicking until I was nearly blind. I am beyond outraged. In desperation, I called the pediatrician for "something stronger" and she prescribed Ovide, which was absolutely horrible. It smelled like turpentine, and the fumes nearly knocked us out. It made us gag, cough and choke, and even caused one of my kids to have a nosebleed. When will the schools and doctors stop perpetuating the lies about these poisons'

Relevant tests/laboratory data

Other relevant history, including preexisting condition

All three of my children have Crohns' disease--a form of Inflammatory Bowel Disease--that is a chronic autoimmune disorder requiring lifelong medication.

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

followed package instructions exactly

Therapy dates

9/29/04 to 11/12/04

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

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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
1401	02/10/1995	female	86 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 10/17/2004 **Date of report** 11/4/2004

Describe event or problem

All products listed in my report did NOT work. Each time after, we discovered nits within days, and after the Nix treatment, which said it could keep you from being reinfested up to 2 weeks, we saw actually live lice on her head. None of these products have helped my child and I don't think that they would. We are now trying olive oil for smothering. It's all that's left without getting a prescrip for Lindane, which I DO NOT want to put on my child.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
R&C and Equate Brand Lice Shampoo

Dose, frequency, route use
R&C used once on Oct 12 Nix used once on Oct 19 Equate Brand Lice

Therapy dates
10/17/2004 to 11/01/2004

Diagnosis for use
Letter sent home from school saying daugther had nits.

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
R&C, Nix and eqaute brand lice shampoo....all used within 3 weeks...from Oct 17 to Nov 1, 2004

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
1394	07/05/1999	female	55 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 10/21/2004 **Date of report** 10/28/2004

Describe event or problem

Medicine caused, what doctor diagnosed as contact diagnosis, but looked to me to be a chemical burning of entire scalp, back of neck, and tops of ears, with blistering. lice returned less than a week later, for the sixth time in six weeks. No reaction the first time medication used.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Ovide

Dose, frequency, route use
used as directed by physisician, using half the bottle per application

Therapy dates
10/05/2004 to 10/21/2004

Diagnosis for use
School reported that child had lice and nits.

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

RID - 9/21/2004
PRONTO - 9/29/2004 & 10/28/2004
Mayonayse - 9/25/2004

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
1393	11/20/1960	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 10/25/04 **Date of report** 10/25/2004

Describe event or problem

Live lice infestation on morning of 10/25. worse than before, even after treatments described below.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell
Nix-1%

Dose, frequency, route use
Nix applied on 10/23/04
Lindane applied on 10/24/04

Therapy dates
10/2304 to 10/24/04

Diagnosis for use
1

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

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
1392	02/03/96	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 10/18/04 **Date of report** 10/25/2004

Describe event or problem

The Kwell (prescription) didn't work. I combed out hair, nits etc...cleaned the house, washed everything put stuffed animals in bag. Dryed pillow each night. Vaccuumed each night. etc.... treated myself and still found a live adult lice on my daughter on Friday 10/22/04. I found a live lice on me Saturday, 10/23/04. Treated Kwell shampoo again. Combing hair nightly, using hair dryer after combing out damp hair. Help!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

My daughter is adhd. Has some breathing problems at times. Over the counter treatments

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

Twice, Monday 10/18/04 & 10/25/04. Enough to wash hair both times

Therapy dates

10/18/04 to 10/25/04

Diagnosis for use

Hope the second dosage worked.

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

no

NDC # - -

Concomitant medical products

Not sure, checking head nightly. Drying hair after combing each night. Drying bedding (pillows, blankets, sheets before bed each nigh) Called school to report head 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

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
1388	05/11/1995	male	82 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 20/00/ **Date of report** 10/19/2004

Describe event or problem

after having been exposed to perithrin my son had an anaphalactic reation we now cary an epi-pen 24hrs a day

Relevant tests/laboratory data

Other relevant history, including preexisting condition

asthma

C. Suspect medication(s)

Name:

perithrin

Dose, frequency, route use

1 time

Therapy dates

2000 to 2000

Diagnosis for use

sister had lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

dont know

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

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
1386	01/04/55	female	138 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: its driving me insane

Date of event 10/15/04 **Date of report** 10/16/2004

Describe event or problem

burning and itching and crawling sensation without picking up any lice or egg. Went to dermatologist. Said to treat as if it is head lice. Daughter has head lice and I have been combing out with nit comb, Rid, etc but we are both overwhelmed with an invisible infestation -- in addition to the head lice??? --that feels like our skin is being eaten from the inside.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

She was born with V.A.T.E.R.s Assn and we are both extremely allergic people

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use

As directed on the package

Therapy dates

10/15 to 10/16

Diagnosis for use

doctor said it was head lice but it isn't responding: itching, [illegible]

Event abated after use stopped or dose reduced

no

Lot #

7430000414

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
1383	11/16/1972	male	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: CAN'T SLEEP

Date of event 10/01/2003 **Date of report** 10/12/2004

Describe event or problem

LICE ALL OVER MY BODY

Relevant tests/laboratory data

Other relevant history, including preexisting condition

N/A

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

2 TWICE A DAY ALONG WITH BATHS.

Therapy dates

1/1/2003 to 10/10/2004

Diagnosis for use

GET RID 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

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
1375	02/17/1997	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 04/04-10/0 **Date of report** 10/1/2004

Describe event or problem

From april 04 thru october 04 my granddaughter has had head lice on and off. We have tried rid,nix,pronto and quell. Nothing seems to work. We comb her hair out almost everyday, cut her hair and still after 5 or 6 days of using a product we see live lice. We are very frustrated.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

She has juvenile diabetes.

C. Suspect medication(s)

Name: Nix kwell,rid,pronto

Dose, frequency, route use

nix about 15times. kwell 2x,rid about 15 times,pronto 2x

Therapy dates

04/04 to 10/04

Diagnosis for use

Doctor suggested nix each week for 6 weeks.

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

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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
1374	01/26/1992	female	100 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

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

Date of event 9/04 **Date of report** 10/1/2004

Describe event or problem

This child used a lice shampoo so often that she got sores on the back of her head and has lost big patches of hair.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None known

C. Suspect medication(s)

Name:

unsure

Dose, frequency, route use

Used once or twice a month

Therapy dates

2000 to 2004

Diagnosis for use

several years of lice shampoo 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

unsure if hair will grow back

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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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
1367	5/18/99	female	32 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 9/23/04 **Date of report** 9/23/2004

Describe event or problem

This was my second treatment with NIX, after rinsing I started combing the louse out and they were still alive. Yesturday the 22nd I combed my daughter twice, morning and afternoon and they were still alive along with today.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: Ovide

Dose, frequency, route use
2nd time

Therapy dates
9/13/04 to 9/23/04

Diagnosis for use
LICE

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

Currently I am combing morning and afternoon.

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
1362	1/17/1994	female	78 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 1999-2004 **Date of report** 9/16/2004

Describe event or problem

My little girl has head lice for years now, affecting school even.I do a run through everyday of her hair. We have even went to a dermatologist, they gave us Ovide (that stuff cant be good for her) I have dyed her haor, I have done it all and they wont go away!!!!!!!!!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Ovide

All of the stuff!!!

Dose, frequency, route use

As much as necessary, at least once a week

Therapy dates

1999 to 2004

Diagnosis for use

NONE WORK!!!!!!!!

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

all medications, as often as possible

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
1360	04/25/92	female	85 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 09/14/04 **Date of report** 9/15/2004

Describe event or problem

Patient was found to have a moderate infestation of head lice (and numerous nits). She was treated with Nix to kill the lice. After the lice were dead and removed, a number of nits remained. We cut her hair considerably shorter and did two treatments with RID egg and nit comb-out gel. After these two treatments and about EIGHT HOURS of combing (with a metal comb, purchased separately; the plastic combs provided with these products are utterly inadequate), the patient STILL had dozens of nits in her hair and could not return to school. There is no question that this is a complete failure of the RID comb-out gel to serve its intended purpose; the instructions were followed to the letter each time. By contrast, and in desperation, we attempted a home remedy for nit removal (a mixture of cooking oil and vinegar) and had considerably more success.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: --

Dose, frequency, route use

Therapy dates
to

Diagnosis for use

Event abated after use stopped or dose reduced

Lot #

Exp. date

Event reappeared after reintroduction

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
1359	06/23/1995	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 09/11/2004 **Date of report** 9/13/2004

Describe event or problem

I treated my daughters hair because her school insisted that I treat with a psticide. The product did not kill the lice.My daughter has asthma. I do not want to expiernce what jesse's mom did.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid
tea tree oil

Dose, frequency, route use	Therapy dates
one bottle of RID and I add tea tree oil to my shampoo.	09/11/2004 to 09/13/2004

Diagnosis for use
There was not an adverse reaction but I am afraid that there

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
1354	11/16/97	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 8/23/04 **Date of report** 9/5/2004

Describe event or problem

I have treated both daughter's hair repeatedly and can't seem to get rid of the head lice

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
rid,nix,vinager

Dose, frequency, route use
once every three to seven days

Therapy dates
8/23/04 to 9/5/04

Diagnosis for use
head 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

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
1351	07/22/1989	female	125 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 05/23/1990 **Date of report** 9/4/2004

Describe event or problem

This child was repeatedly treated for lice from the time she was a baby till she was removed from her mothers home wen she was 2 or 3 (not sure what age). I didn't have close communication with her again until the past couple of years and she is still getting lice. She is 15 now and has learning disabilities and behavior problems and speech problems, and I don't even know what kind of physical problems she may have.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid
Nix, tea tree oil, generic lice treatment

Dose, frequency, route use
When she was a baby, after her parents split up, every time she came to visit her

Therapy dates
1989 to 1992

Diagnosis for use
i don't know how to answer

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
1348	06/07/1998	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 8/7/04 **Date of report** 9/2/2004

Describe event or problem

treated with Nix, Rid twice, and Kwell twice and still found live lice (most small, but some adult size) After manual removal, another infestion 2 weeks later treated with olive oil this time. Still finding live lice.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
shampooed every night for a week

Therapy dates
8/7/04 to 9/2/04

Diagnosis for use
lice killer

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

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
1347	08/19/94	female	54 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 08/01/04 **Date of report** 8/31/2004

Describe event or problem

We discovered head lice on our daughter after she had complained for two weeks of itchy head. We thought she had a dry scalp from swimming in the pool so much. About two-three weeks after her first complaint, she asked me to just please scratch my head mommie and I then realized she had maybe 50 head lice and probably 500 eggs in her hair. We treated her head with RidX, olive oil, permethrin 5%,Ovide 0.5% and with the anitbiotic bactrim. As of today, I am still pulling live lice off of her head. I have washed everything, vaccumed the entire house twice a day for the last 9 days and sprayed probably 4 cans of lice spray.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

She currently has seasonal allergies.

C. Suspect medication(s)

Name: malathion
permethrin 5%, olive oil, lice sray

Dose, frequency, route use	Therapy dates
malation 0.5% used 3/4 of a bottle,permethrin 5% 1 dose, RidX 1 dose, olive oil	8/24/04 to 8/30/04

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
1346	11/09/62	female	110 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 08/04/ **Date of report** 8/30/2004

Describe event or problem

Inflammation of scalp, along hairline, ears, and neck. Breakout resembling acne on neck which is still visible on neck. Burning and itching for several days. Small blisters appeared at hairline. Skin on neck and ears very red and scaly looking. I had used the product on both my daughter and myself.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Sensitive and highly allergic to poison ivy, poison oak. Had excema during pregnancy thought to have been brought on by laundry detergent/bleach

C. Suspect medication(s)

Name:

Rid Pure Alternative lice and egg remval system

Dose, frequency, route use

4 ounce bottle in kit. Used about half the bottle as instructed (2-3ou) for my

Therapy dates

8/10 to 8/10

Diagnosis for use

headlice, both nits and live bugs found on my daughter.

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

NDC # - -

Event reappeared after reintroduction

doesn't apply

Concomitant medical products

none. Product was used one time only. Product contained Demethicone.

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
1342	12/94/	female	79 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 8/24/04 **Date of report** 8/27/2004

Describe event or problem

Treated her with Nix exactly as directed. Two days later observed several very small live lice. Treated that day with Ovide.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
8/24/04 1 dose

Therapy dates
8/24/04 to 9/2/04

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
Ovide on 8/26/04

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
1340	08/10/1998	female	54 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 08/12/04 **Date of report** 8/23/2004

Describe event or problem

Everthing we use does not remove the eggs or lice.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
Ovide

Dose, frequency, route use
Lindane .05 once
Ovide used once weekly for
2 times

Therapy dates
08/12/04 to 08/23/04

Diagnosis for use
Lice Infestation

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
1338	01/01/63	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:

Date of event 19/84/ **Date of report** 8/20/2004

Describe event or problem

premature labor following the use of lindane lotion

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

applied neck down and left on over night

Therapy dates

4/16/1984 to 4/17/11984

Diagnosis for use

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

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
1332	02/14/1995	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 8/11/2004 **Date of report** 8/12/2004

Describe event or problem

On 8/10/04, I treated my daughter with NIX head lice treatment, as directed - the next morning (8/11/04), she woke up with a runny/stuffy nose and a sore throat. Then today, 8/12/04, I found another live lice, an indication that the treatment did not work

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
One bottle(2 oz)was used, one time, completely saturating hair and onto scalp

Therapy dates
8/10/04 to 8/10/04

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

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
1328	01/26/95	male	80 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	1/26/95	Date of report	8/7/2004

Describe event or problem

Nix and Rid were used by mother very early in pregnancy. Child is developmentally disabled. Has moderate Mental REtardation and sensory integration disorder.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Nix

Rid also

Dose, frequency, route use	Therapy dates
Used on self 4 or 5 times, as well as treating 4 other family members	4/94 to 5/94

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 believe I reported her case several years ago. I would really like information if others have had similar things happen

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
1317	10/31/1969	male	185 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

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

Date of event 7/18/04 **Date of report** 7/20/2004

Describe event or problem

Suffered mild nausea and headache after using an OTC lice spray (Pronto « Lice, Tick & Flea Killing Spray) inside a passenger vehicle, after an outbreak of headlice. Waited 2-3 hours after application before using vehicle, vehicle was ventilated after application. Symptoms subside several hours after leaving vehicle, but reappear each time vehicle is used.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Pronto

Dose, frequency, route use
1/3 ~ 1/2 of 6oz aerosol can. one application

Therapy dates
7/18/04 to 7/18/04

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
1314	08/20/1982	female	160 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

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

other: live lice found on head

Date of event 07/04/ **Date of report** 7/19/2004

Describe event or problem

After treating herself 5 times with both over the counter remedies as well as prescription Lindane, and despite washing everything she owned in hot water and drying it all in hot dryers, my daughter, Alicia Bowen, still had live lice on her hair and head.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

My daughter has a seizure disorder (preexisting).

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

2 times in 2 weeks

Therapy dates

07/05/04 to 07/18/04

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

My daughter has been treating herself for lice for two months with no success.

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
1313	06/05/1995	female	115 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 03/04-07/0 **Date of report** 7/18/2004

Describe event or problem

reoccuring lice problem Quell and otc products not working even after cleaning house combs brushes and all bedding in the house. Ive also did baby oil and saran wrap all night long. Ive never seen a live bug in my daughters hair. But she has had the nits 3 time in the last six weeks.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name:

Our Family lice shampoo, Baby oil

Dose, frequency, route use

once at finding them then 7 days later

Therapy dates

03/07 to 2004

Diagnosis for use

Head lice nits.

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

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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
1306	04/22/1944	female	220 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 07/04/04 **Date of report** 7/5/2004

Describe event or problem

got lice from grandchildren. used permethrin 1% on 6/25. found live lice on 6/26.used nix. 2 visits to doc. first said it was dry skin perscribsd selenium sul2.5% i didn't use.(had lice)!second doc. said use permethrin 1% again,i did today 7/4/04 after doing hair removed adult live louse. still have live lice. hair is very long,head is full of open sores from scratching and my neck has big swollen hard lumps lymphnods i assume. HELP!!!!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
permethrin 1%

Dose, frequency, route use
used 3 different times

Therapy dates
6/25/04 to 7/04/04

Diagnosis for use
kill lice and nits

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

Lot #
L312083 & 1G2581(on nix)

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
1301	09/07/2000	female	33 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 06/07/2004 **Date of report** 6/21/2004

Describe event or problem

Used nix. Irritated the scalp (chemical burn?) four days later both live adult louse found. Used Rid day 10, further irritated scalp. skin at top of head crusted and peeling. bright red areas. Lice still a problem.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
also rid, using mayo and loive oil with combing no

Dose, frequency, route use
Nix used. failed. used oils every other day til day 10 then Rid mousse. Still using

Therapy dates
05/18 to 6/21

Diagnosis for use
lice found on mom and daughter. intense itching, eggs. Nymphs.

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

between treatments of pedilucides, used il and mayo and coconut shampoos. Car seats vaccummed daily after use and stem cleaned twice. Al bedding washed daily in 135

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
1294	08/29/1992	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 05/29/2004 **Date of report** 5/30/2004

Describe event or problem

we have been trying to get rid of the lice for a few years. (off and on) I simply shave my son's head, but my daughter is the one I can't get rid of the lice from. This tells me it is a nit removal problem.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Ovide

I have also used generic, RID, NIX, Tree oil

Dose, frequency, route use

5-6 times this year alone

Therapy dates

2000 to 5/29/2004

Diagnosis for use

nits and lice detected in her hair

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
1293	07/01/2000	female	35 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 05/10/2004 **Date of report** 5/26/2004

Describe event or problem

For almost a year we have been fighting lice either my daughter has it or I have it. We get rid of the lice then about 2-3 weeks later she has them again. I've tried Rid, Nix, Pronto Plus, and the Dr. prescribed ovide 0.5%. I use the nit comb and follow instructions. I am so tired of fighting a loosing battle I'm almost to the point of shaving both mine and my daughters head. She will be starting school in the Fall and they have a nit free policy. Please help.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Ovide
nix

Dose, frequency, route use
alternating brands 7-10 days

Therapy dates
06/01/2003 to 05/25/2004

Diagnosis for use
left on 10 minutes as directed and left ovide 0.5 on for 8 hours

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

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Pronto Plus, vaseline, 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

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
1292	12/2/83	male	90 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

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

other: ADD/Panic Anxiety

Date of event 31/71/992 **Date of report** 5/25/2004

Describe event or problem

At age 10 my son was treated for scabies with lindane. He was treated between 3/17 - and 3/31/92 also 11/03/95 The prescriptions we filled 3/17 and again on 3/28. I treated myself and daughter as well as Darin by applying the lotion all over - due to the fact that even though Darin was the patient diagnosed - myself and daughter also felt contaminated and itched. I was never instructed about the dangers of the drug -

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Now, some 10 years later - Darin continues to be on aniety medication (paxil & Wellbutrin) and I was treated for breast cancer in 7/2001. My daughter is also on anti depressents and just recently had tests run due to abnormal pap smear reports. A tissue sample was taken and as of this date 5/25/04 - we are awaiting word on the outcome. My cancer was estrogen positive and I elected to have a bilateral mastectomy in 12/01. My question is do I need to pursue looking into the fact that we can be contaminated and that could actually be the cause of our problems.

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
Couple of times a day

Therapy dates
3/17/92 to 3/31/92

Diagnosis for use
scabies

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

I would appreciate any comments that you may have relating to this situation and if I need to look into this further. Thanks. Donna Wells 202 Barden Drive,

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
1289	04/22/1989	female	45 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: see "event or problem" below

Date of event 12/19/97 **Date of report** 5/18/2004

Describe event or problem

caused heart palpitations, and an asthma attack, and shaking in limbs
in parent spraying mattress

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Asthma in parent

C. Suspect medication(s)

Name:

RID Spray

Dose, frequency, route use

Sprayed mattresses

Therapy dates

12/1997 to 01/1998

Diagnosis for use

lice in aforementioned child

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

Eucalyptus oil mixed with water- no reaction, and lice seem to DISLIKE
it a lot.

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
1288	09/03/1981	female	155 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: sever rash

Date of event 05/03/2004 **Date of report** 5/18/2004

Describe event or problem

my 2yr old daughter got lice and gave it to the family. we had to shave her head. now i cant get rid of them i have cut my hair 3 times used lice kits, mayonasie, baby oil and no matter how much i do its just not enough. my daughter got a really bad rash from the lice kit i used on her, now she has sores all over her head and back. i feel like i am at my wits end with this it has been about 2 weeks, i am on the verg of shaving my head to get rid of the lice. i never gad this as a child and it makes me feel so dirty. i just want everyone to know that lice kits may harm your kids so read everything you can before you hurt them.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

i have m.v.p a heart condition.

C. Suspect medication(s)

Name:

equate lice kit

Dose, frequency, route use

used twicwe on my head

Therapy dates

05/03/2004 to 05/18/2004

Diagnosis for use

to treat 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
1284	12/30/1994	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: 3mm tumor on pituitary gland

Date of event 8/2002 **Date of report** 5/6/2004

Describe event or problem

my daughter got headlice. we used over the counter lice treatments such as NIX and RID and also used lindane. We used them repeatedly over a 6-9 month period about once a week to try to get rid of the lice. the treatments were unsuccessful. My daughter started getting headaches around that time and she then began to develop a breastbud (age 7). The dr performed a MRI scan which determined she had a 3mm tumor on her pituitary gland. I was too embarrassed to mention the lice treatments we had been using and didn't think they were related initially..however we stopped using the treatments and about 6 months later the tumor since disappeared. Two follow up MRI's have been performed and now there is no tumor. I believe the lice treatments caused the tumor.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
1 bottle approx once a week

Therapy dates
08/2001 to 08/2002

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

RID..used both NIX and RID 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
1271	04-25-68	female	115 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

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

Date of event 04-12-04 **Date of report** 4/13/2004

Describe event or problem

I sprayed my daughter's mattress with Lice-Free spray and it made a horrible smell that would not go away and gave me a terrible headache. I just delivered a baby 3 weeks ago and am concerned about everybody in my family. I can't get the smell out of the mattress or the pillows. My 8 year old complained of feeling nauseus at same time I had horrible headache.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

My 8 year old had been treated with NIX the same day.

C. Suspect medication(s)

Name: Nix
Lice-Free Spray

Dose, frequency, route use
once

Therapy dates
04-12-04 to 04-12-04

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
1268	07/10/57	female	180 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: you tell me

Date of event 2000-2001 **Date of report** 4/6/2004

Describe event or problem

Can someone please tell me how a doctor can precribe something so dangerous as these Lice treatments and how they can be sold over the counter. I was shocked at the hazards and I had no knowledge of the dangers or would never have used them on my family and myself. I treated my family while being treated for breast cancer which I didn't have prior to what we nicknamed the plague of 2000 which lasted into the spring of 2000. James was sent home from school in October of 200 with head lice and shortly after that I developed breats cancer. Found a lump in November 200 treated in 2001. I guess I will never know huh? This is very frightning. I will never again purchase these products. They didn't work any way. Constant combing and grooming and checking and mayonaise and olive oil. We would treat our hair get rid of them (we

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

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

Dose, frequency, route use
each one once then follow up in 7 to 10 days leave on ten minutes

Therapy dates
10/2000 to 05/2001

Diagnosis for use
use to treat 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

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
1267	06/26/1996	female	42 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

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

other: severe ongoing bronchoitis

Date of event 02/20/04 **Date of report** 4/5/2004

Describe event or problem

Lice problem started in January 2004 at school. Both of my daughters, despite proper treatment at home, kept coming home eith lice. Which meant repeated treatments with the shampoos. My 7 year old has now had bronchitis 3 times, missed 26 days of schools. She is on Xopenex, Pulmicort, Advair, Singulair, she was on Orapred for a week and she also uses Nasalcort. She has never had problems like this before.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
Rid, Pronto

Dose, frequency, route use
every 7 days

Therapy dates
01/2004 to 02/2004

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

Products were used sporadically in late 2003 after school started but the bulk of the use was in January and February

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
1264	05/04/1997	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: Out of school

Date of event 03/15/2004 **Date of report** 3/31/2004

Describe event or problem

She has had lice for about 6 months off and on, they keep coming back and the nix is not working to kill the live ones anymore

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

one bottle every other week

Therapy dates

10/01/2003 to 03/31/2004

Diagnosis for use

Head lice

Event abated after use stopped or dose reduced

no

Lot #

unkn

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

rid 10/01/2003
nix 11/01/2003
nix every month there after

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
1262	06/24/1969	female	210 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

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

Date of event 03/13/2004 **Date of report** 3/21/2004

Describe event or problem

I used a lice treatment shampoo from albertsons grocery store (it was their brand) and in the 8 days following the treatment I have had severe head itching and swollem bumps under my skin at the base of my skull.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: generic lice shampoo
sav-on osco by albertsons

Dose, frequency, route use
maximum strength used once

Therapy dates
03/13/2004 to 03/13/2004

Diagnosis for use
trreatment of head lice

Event abated after use stopped or dose reduced
no

Lot # 3f19b

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
1254	11/13/1999	male	31 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 2/26/04 **Date of report** 3/3/2004

Describe event or problem

recurring head lice. Have been treating three girls plus myself for two months, spending well over $100 in treatments. Dr's refuse to prescribe Kwell, I would refuse to use it anyways. I have ordered an organic treatment as of today; meanwhile, our heads are chewed up from the scratching, and there is no relief in sight.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
Rid

Dose, frequency, route use
Every week since mid-January

Therapy dates
01/10/2004 to 03/02/2004

Diagnosis for use
head lice treatment

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
Rite Aid Brand treatment

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
1253	8-14-69	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 2001-2004 **Date of report** 3/3/2004

Describe event or problem

You really should have enough for 2(two)treatments in the first purchase

Relevant tests/laboratory data

Other relevant history, including preexisting condition

In 1988, My daughter, husband and I moved to India.(1yr.4 mo.) When we returned to the US I was very sick. I was diagnosed w/HEP B- or HEP nonB. This is now HEP C., and is viral. Do lice, etc. know when someone has one foot in the grave and the other on a banana peal? Do they persist on the victim when their time is short? Do they detect that death is near? Maybe by smell?

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use
1 bottle

Therapy dates
10-02 to 3-04

Diagnosis for use
n/a

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

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
1251	03/03/01	female	35 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 01-12-04 **Date of report** 3/1/2004

Describe event or problem

Multi use of product, no results HELP!!!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
Nix

Dose, frequency, route use
2 Oz on me and daughter, i am 25 125 lbs

Therapy dates
01-12-04 to 02-29-04

Diagnosis for use
no results

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
1247	01/05/54	female	125 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 03/20/03 **Date of report** 2/19/2004

Describe event or problem

Heart racing, ultra-sensitive to light and sound, difficulty controlling emotions, possible convulsions

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I was feeling stress after 3 months of isolation and still having reinfestations after treatments

C. Suspect medication(s)

Name: Nix
Kwell,Rid, pest. spray,

Dose, frequency, route use
Shampooing and spray treatments every 3-5 days on 3people and a dog and the

Therapy dates
03/2003 to 06/2003

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
1246	07/15/1975	female	145 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 08/20/01 | **Date of report** 2/17/2004

Describe event or problem

In '01 I treated my daughter with lindane, for headlice, she was 5 years old at the time. Prescribed by peditrican. I was pregnant at the time. At 36 wks I developed a liver disease, which caused me to deliver my baby 4 wks early. At the time my baby was born, she did not have a heartbeat. It took the drs. 17 mins. to revive her. She suffered with a few seizures and spent 1 week in the NICU at an area's childrens' hospital, then an add't 4 weeks at the same hosp. I spent 11 days in the hospital as well.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

Applied to infected area, hair on head. Approx. 5 or 6 times in a period of 1 to 4

Therapy dates

08/2001 to 10/2001

Diagnosis for use

Headlice: treat all family members.

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
1241	03/06/1994	male	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: re-treatment

Date of event 1/04-2/04 **Date of report** 2/12/2004

Describe event or problem

my son had head lice and was treated with Nix shampoo, a week later i brought him back to the doctor and he still had it so the doctor perscribed Acticin, he said to put it in our hair for 14 hours with a shower cap over our heads. I also did this for me (115 lbs, 28 yrs old) and my daughter (32lbs, 2 yrs old). I have been reading about benzene and Lindane. All 3 of us were treated with Nix shampoo for 10 minutes and Acticin for 14 hours a week later. Should I be worried about anything?? I called my doctor with concerns and he said that Acticin does not contain Lindane. How do I know if my kids and my self are going to be alright? What should we use then to get rid of the lice?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

My son has asthma, my daughter became sick with a cough, congestion, runny nose, watery eyes, the doctor said she just had a cold.

C. Suspect medication(s)

Name:

Acticin and Nix

Dose, frequency, route use

Nix was used 10 minutes, one time use. (I used the Nix 2 different times in 1 week)

Therapy dates

01302004 to 02062004

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

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
1238	01-29-1998	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 11-20-2003 **Date of report** 2/4/2004

Describe event or problem

head lice returned ?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

once every 7 days

Therapy dates

11-20-2003 to 02-04-2004

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

lice be gone
mayonaise treatment
safetek

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
1233	03/29/1993	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 12/22/2003 **Date of report** 12/29/2003

Describe event or problem

I have used RID, NIX, and prescription Lindane, to still find Lice present!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
RID

Dose, frequency, route use
As directed

Therapy dates
12/05/2003 to 12/28/2003

Diagnosis for use
head lice

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

Lot #
unknown

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

Tried mayonaisse, and reapplying over the counter medications

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
1230	07/04/1998	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: burning/itching rash and hives

Date of event 10/09/2003 **Date of report** 12/16/2003

Describe event or problem

I used, out of utter desperation mind you.. Kwell. Her head starting burning and itching immediately. She complained of numbness in her right foot. As I tried to rinse it off her head.. any part of her body it touched caused burning and itching.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
1oz one time

Therapy dates
10/9/2003 to 10/9/2003

Diagnosis for use
Lice--head

Event abated after use stopped or dose reduced
yes

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
1223	6/25/97	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 20/03/ **Date of report** 11/30/2003

Describe event or problem

I have been having a lice problem with my daughter for the whole year of 2003.I have used every medication on the shelf at pharmacies,and been to the Dr. and prescribed meds.She has missed a numerous amount of school and I still cannot control the problem.The other family members have had no problem with it.Excluding myself which I feel I have it now also.I have used frequently Nix and Rid.I have used lice egg remover creams,a spray that is supposed to allow you to better see the eggs for removal.I have sprayed my home,thrown away several bed linens,bagged up all unwashable items.Used a lindane shampoo prescribed by a Dr.On 4 occasions and still have this problem.Please Help me!! I am going to go to jail for her missing school and she is going to fail.Not to mention she is extremely uncomfortable and keeps a rash on the back of her neck and behind her ears

Relevant tests/laboratory data

Other relevant history, including preexisting condition

N/A

C. Suspect medication(s)

Name:

lindane,rid,nix ,clear

Dose, frequency, route use

2 to 3 times a month

Therapy dates

1/2003 to 11/2003

Diagnosis for use

head lice was seen,constant itching,rash

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

I have listed them all above.None of them are working.

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
1214	08/14/1974	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:

Date of event 11/11/2003 **Date of report** 11/11/2003

Describe event or problem

product failure and nothing saying not to use while nursing it made by baby sick

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix rid

Dose, frequency, route use
4 oz two seperate applications

Therapy dates
11/02/2003 to 11/11/2003

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

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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
1207	08/04/95	female	80 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: rested at home

Date of event	20/01/	Date of report	10/17/2003

Describe event or problem

Treated with Lindane, the 3 kids and myself. We all felt nauseaus, dizzy, headaches. A result of leaving it on to long.I was sure I had monitered properly.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use	Therapy dates
aprox 20 ml of solution, used twice only	2000 to 2000

Diagnosis for use	Event abated after use stopped or dose reduced
constant lice, large and small,many nits & bites	yes

Lot #	Exp. date	Event reappeared after reintroduction
		doesn't apply

NDC # - -

Concomitant medical products

Nix R&C Kwel Pronto all been used over the years 2000-2003 about 2 shampoos a month/month and a half with breaks in the summer, they seemed to go away. School

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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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
1202	06/27/1992	female	163 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: increased allergies/lifelong problems

Date of event 07/19/94 **Date of report** 10/14/2003

Describe event or problem

Rebecca (and her sisters) was treated no less than 4 times in a row using RID and NIX products, including bedding spray, in the months of June, July and August of 1994. I believe that these repeated treatments caused her extreme allergies and have contributed to several bouts of bronchitis.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Rebecca was a toddler and then a two-year old in the day care program in which this occurred. We removed her and her sisters from the program when it became clear that the day care would not accept responsibility for cleaning up its own facilities and ending the exposure to the children onsite. They chose to blame the parents instead of take responsibility. Rebecca did not have allergies before this time, but developed them shortly thereafter (within the next two years).

C. Suspect medication(s)

Name: Nix
Rid

Dose, frequency, route use
Shampoo and bedding spray (sprayed on bedding, in car, on carpets, on sofas

Therapy dates
06/1994 to 08/1994

Diagnosis for use
That she had head lice and needed to be treated with these products

Event abated after use stopped or dose reduced
no

Lot #
unknown

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

There were at least four other times in the next four years, where she had to be treated for lice and we always used either Nix, or Rid, Shampoo and spray (with combing and

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
1196	02/20/98	female	43 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 09/26/03 **Date of report** 10/6/2003

Describe event or problem

I wasn't aware of dangers involved with treatments. I have had to treat my children several times in the past couple weeks now, including sprays and shampoos. All three of my children have been sick and missing even more school inbetween missing school from returning home with head lice over and over..

Relevant tests/laboratory data

Other relevant history, including preexisting condition

My daughtor Laney whom is the one that keeps getting the lice.. also has bites all over her body almost like a really bad case of flea bites? I do have two dogs but have also done all i can just incase it is flea bites? Although my other children do not have these marks...It does seem that the break out on her happened around the same time i started treating her for head lice..Is it possible it is a diff kind of lice?

C. Suspect medication(s)

Name: Rid
also NIX

Dose, frequency, route use
have done at least six treatments that is meaning ~~double two ounce treatments~~

Therapy dates
09/23/03 to 10/06/03

Diagnosis for use
Live 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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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
1194	11/28/1987	female	325 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 1999-2003 **Date of report** 10/3/2003

Describe event or problem

lice did not die. my head broke out and my hair started to fall out.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

asthma and excema

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
every 10 days

Therapy dates
1999 to 2003

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
1189	6-22-95	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 8-12-03 **Date of report** 9/17/2003

Describe event or problem

the headlice will not go away

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

wash hair 2times

Therapy dates

8-12-03 to 9-12-03

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

nix,rid still had 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

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
1184	03/26/1968	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: shaved head

Date of event 08-24-2003 **Date of report** 9/12/2003

Describe event or problem

I am still battling with head lice. It will be three weeks Sunday. I have washed my hair atleast 18 times with over the counter products such as: RID, NIX, and Permethrin. After these failed I was prescribed Lindane and then Ovide. These too were BIG failures. (I followed the directions completely!) The lice were chemically resistant! After each product was rinsed out, I would check my head only to see them scurrying around. It sickens me to think about these dangerous products I have put on my head especially when they DON'T WORK! I have slept with olive oil and mayonnaise on my head. I have combed with conditioners on, I have combed with oils and vasaline, I have also combed with dry hair and wet hair. I recently had my husband shave my beautiful, long and thick hair down to a quarter inch to aid in getting rid of these horribly resilient

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None known

C. Suspect medication(s)

Name: lindane
malathion

Dose, frequency, route use
1% and 0.5% both were applied twice.

Therapy dates
08-24-2003 to 09-12-2003

Diagnosis for use
head lice

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

Lot #
unknown

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
NIX, RID, Permithren

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
1180	01/18/1999	female	40 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

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

Date of event 9/01-9/03 **Date of report** 9/9/2003

Describe event or problem

I have tried everything. I have cut almost all her hair, I have used all the products on the shelf. I have used the robicomb. I have used tea tree oil and tea tree oil shampoo. I have used mayonaise, and olive oil. HELP!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name:
all on the list except kwell and lindane

Dose, frequency, route use
recommended on package

Therapy dates
9-2001 to 9-2003

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

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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
1179	07/02/1961	female	218 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

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

other: missing work

Date of event 8/06/03 **Date of report** 9/7/2003

Describe event or problem

Scabies, was gotten by infant grandson who got them from a mothers friend and now whole family has them... Was treated by dr. twice but has been reinfested we did everything that the Dr. said to do....

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Has high Blood Pressure and diabeties

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

the Lindane lotion 1% use 1 time and the Acticine cream 5% use 1 time

Therapy dates

8/06/03 to 8/24/03

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

Acticine (permethrin) cream 5%
8/12/03 and 8/18/03

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
1178	09/25/95	female	60 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

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

other: sores on her head

Date of event 5/2003 | **Date of report** 9/3/2003

Describe event or problem

child sent home with head lice

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Nix

you name the brand we tried it

Dose, frequency, route use

as directed

Therapy dates

05/03 to 09/03

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

NDC # - -

Event reappeared after reintroduction

doesn't apply

Concomitant medical products

we have tried every treatment available from ones containing pesticides to herbal remedies with no positive results

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
1171	04/26/1990	female	100 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 1996-1998 **Date of report** 8/7/2003

Describe event or problem

My daughter, Rebekah was 7 years old when she first had headlice. Her and her sister, Stacey is half black and half puerto rican, so I thought headlice would not be a big problem for my girls. She had contracted head lice from her daycare center, and what I thought would be a little problem turned out to be a battle for a year and a half. Although Stacey never contracted head lice, Rebekah seemed to attract them by the hundreds even after numberous shampooing with every product on the market. I even tried all the natural ways of getting rid of these little bugs that cause so much damage. The more I tried, it seemed they never would die. I literally washed and shampooed and sprayed day in and day out for a year and a half before I finally had to move. Once I finally moved, then slowly but surely did Rebekah get released from the prison she was

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Heart Disease (Pulminary Stignosis)

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use

Dosage: every 2 weeks for a year and a half. I also washed everything every

Therapy dates

1996 to 1998

Diagnosis for use

shampoo every 10 days

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, Maynaise, Clear, Vaseline, Tee Tree Oil, Olive Oil, Vinegar, mixture of conditioner and a small amount of bleach (I was desperate).

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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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
1157	08/08/1998	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 07/11/2003 **Date of report** 7/11/2003

Describe event or problem

after treating with both over the counter products and prescription shampoo live lice returnedin 3 weeks

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Rid
lindane

Dose, frequency, route use
twice with the rid/ twice with lindane over a 3 week period

Therapy dates
6/20/2003 to 7/11/2003

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

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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
1153	4-4-1967	female	112 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: depression and missed significant work lost wage

Date of event 10/5/01 **Date of report** 7/7/2003

Describe event or problem

Treated for scabies with Lindane Shampoo. Migrane three days later so bad I went to the emergency room.

Still had bumps and itching but roomate and her son did not. Hairlike fuzz, Bites, sores developed, feel movement, see migration when I stretch skin,
Reoccurring now for two years and worse every time. Seen 12 doctors in two years and still no diagnosis even with cloearly visible parasites and eggs in stoole, urine, menestration blood, sklin lesions, dust balls, hair moves with no air. Dog affected as well. Environment contamination like scabies but no one who stays at my house gets it!!! Registered at Morgellons.com. That is what I have and I pary for help getting this diagnosed and cured before I lose everything I have worked so hard for.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I have no spleen (car accidnet at age 16)

My friend who has this as well is from Terre Haute Indiana and
had an apendictimy at age 7 or 8

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use	Therapy dates
5 minutes then shower. I re-trated a couple times the following week. Roomate	10/75/01 to 10/7/01

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

antibiotics, keflex, metrodiazadol (three times), 15 types of cortizone creams, prednisone, difluxican, Herpes zoster med zovirox for 5 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

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
1143	03/07/1956	female	110 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 04/15/2003 **Date of report** 6/22/2003

Describe event or problem

Still have not gotten rid of them.
Shampoo use 5 times, Hair conditioner treatment 2 times, Elimite 3 times - secondary infection and massive hair loss.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid
nix, generic and elinimite

Dose, frequency, route use
shampoo 5 times elinimite 3 times

Therapy dates
04/15/2003 to 06/22/2003

Diagnosis for use
head lice although Dr's have never found any nits

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
antibiotic for secondary - doxipen for allergic reaction, biopsy, my 8 year old got them end of May and they just don'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 # _____
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

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
1142	06/22/54	female	160 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 4/03-6/03 **Date of report** 6/21/2003

Describe event or problem

Nix (multple applications), Ovide (two overnight applications) alcohol baths (10-15 minute soaks) each day for a week, strong salt solutions (10-15 minute soaks each day for a week), repeated combing with Rid metal fine tooth comb all failed over 3 month treatment period. OTC and prescription products used strictly according to instructions. OVernight olive oil soaks X2 ineffective.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

patient is a health physician

C. Suspect medication(s)

Name: Ovide

Dose, frequency, route use

One bottle worn overnight til dry each week for 2 weeks

Therapy dates

4/03 to 6/03

Diagnosis for use

head 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

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
1139	04-08-52	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: Called ER for help

Date of event 06-06-03 **Date of report** 6/13/2003

Describe event or problem

Rapid heart rate, dry cotton mouth, no appetite, weakness, burning scalp

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Had what we thought were head lice and used RID which didn't work and then got prescription for lindane.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
Used only once

Therapy dates
06-06-03 to 06-06-03

Diagnosis for use
? body 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

Bayer Alternative RID for combing

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
1138	10/17/1996	female	53 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 06/02/03 **Date of report** 6/12/2003

Describe event or problem

I have been fighting head lice for 18 months. We'll go for 5-10 days w/out a problem, then all of a sudden she is scratching & I will check & there are live lice in her hair. I don't do things half way. I have spent many nights, 4 hours at a time going through her hair to make sure that the nits & live lice are gone & still, to no avail. I have used Nix, Rid & Lindane (3 times in the last 18 mos. & after reading what I have read tonight, that scares me) all 3. After we rinse it all out, they are still crawling & alive. I am meticulous in going through her hair to remove the lice & nits, washing & drying everuything for at least 30 minutes, (most times 50 mins), vacuumming, mopping, to make sure they're gone. I even blow dry her hair, for the pure heat of it all for a solid week after the fact. Still, we have this problem. Will you please tell me how to stop it?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

N/A

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
Once every 7-10 days

Therapy dates
06-02-03 to 06-12-03

Diagnosis for use
Consistant head Lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Nix & 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

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
1136	10/28/96	female	47 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 12/20/02 **Date of report** 6/9/2003

Describe event or problem

I have tried to eliminate lice with rid, nix, lindane, mayonaise, baby oil, picking combing constantly. just when i think i have it under control their back. after using treatments i still find live crawling bugs!!!!help

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
nix,generic,mayonaise,baby oil,rid,

Dose, frequency, route use
periodically

Therapy dates
12/2002 to 6/2002

Diagnosis for use
no help

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
1133	08/12/74	female	125 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 05/08/03 **Date of report** 5/18/2003

Describe event or problem

I noticed red marks on my neck after staying over at a friends house who has a ferret. There was a mark on my arm that appeared to be a bite mark so I went into a walk in clinic . They prescribed me a cream called acticin because she said it looked like I had scabies. I put it on from the neck down but the red marks are starting to appear all over my body starting from my neck to my feet. Please let me know what I should do.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I have allergies to many things but I believe the allergies would have happened all at once, not in sections at a time.

C. Suspect medication(s)

Name:

acticin

Dose, frequency, route use

once all over body from neck down.

Therapy dates

05/12/03 to 05/12/03

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

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
1130	02/18/98	female	4 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 11/3/2000 **Date of report** 5/12/2003

Describe event or problem

After appication of OSCo Lice Treatment Shampoo, 2 1/2 year old Amber McKeown experienced immediate respiratory and skin reaction resulting in emergent treatment, intubation, and ultimately death from respiratory failure.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: OSCO Lice Treatment Shampoo

Dose, frequency, route use: 1 application

Therapy dates: 11/3/2000 to 11/3/200

Diagnosis for use: lice

Event abated after use stopped or dose reduced: yes

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
1129	12/07/76	female	158 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 10/20/01 **Date of report** 5/12/2003

Describe event or problem

At onset about 17 children in my first grade classroom were diagnosed with scabies. I was also diagnosed and then given a perscription for a cream product. Having had scabies two years prior and successfully treated it using the same cream I was sure it would go away. After three months and three subsequent treatments later, I found myself not better but worse.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

It seemed that the scabies had moved onto my head. Although my doctor said that this was impossible. I itched all over and it got substantually worse at night so I bwegan to loose sleep. My doctor sent me to a dermatologist who determined that I probably never had scabies but that I had hives. From there to a hives specialist who said I didn't have hives. Back to the derm. who said I was depressed. Back to my family doc. who perscribed an antidepressant and suggested I go see a counselor. 9 months later I have finished with therapy and discontinued taking antidepressants but to my doctors amazement my skin

C. Suspect medication(s)

Name:

none of these have seemed to work for me and I ha

Dose, frequency, route use

I spent over $3000 dollars last year on perscriptions alone to try and rid myself of

Therapy dates

10/2001 to 04/2003

Diagnosis for use

Scabies, parasite, unknown skin condition, hives

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
1127	05/02/1998	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 05/09/2003 **Date of report** 5/10/2003

Describe event or problem

3 products were used: a generic, Nix and Lindane and live lice were still present.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

as recommended

Therapy dates

05/03/2003 to 05/10/2003

Diagnosis for use

from doctor, in the case of Lindane

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

in comments 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

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
1126	07-14-03	female	160 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

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

other: missing school, having head lice off and on for ov

Date of event 20/03/ **Date of report** 5/4/2003

Describe event or problem

We have a big family. Alot of kids 3 families. 13 kids and one or two keep head lice at all times. Its a vicious cycle. And I am at my wits end. Also its like torture to comb out the bugs and nits on each and everyone of the girls. They cry when anyone even mentions the lice comb. My youngest grandaughter has thick hair and her scalp is very hot, so the lice bugs love her. She has had lice for over a year and we just can't get rid of them . Please help.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Can't get rid of lice.....

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use

4 or 5 times a year

Therapy dates

1999 to 2003

Diagnosis for use

head lice boo coo

Event abated after use stopped or dose reduced

doesn't apply

Lot #

n/a

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

achol and 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

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
1121	11/15/1995	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: don't work

Date of event 20/01/ **Date of report** 4/26/2003

Describe event or problem

I have three kids we all have had lice for about two years now. I have done every thing(over counter,kwell,ovide,you name it)

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name:

all

Dose, frequency, route use

every two weeks and have given up

Therapy dates

2001 to 2003

Diagnosis for use

?

Event abated after use stopped or dose reduced

no

Lot #

?

Exp. date

Event reappeared after reintroduction

no

NDC # - -

Concomitant medical products

all

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
1120	5-6-92	female	170 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: doctors prescribing extra medication for the asth

Date of event 4-03-03 **Date of report** 4/25/2003

Describe event or problem

Have treated my daughter several times with NIX and it has caused terrible asthma attacks. The product does not kill the lice and the retreatments have made her worse with the asthma.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

She has had asthma since she was two and I did not anticipate that the lice product would cause it to be worse. Nix does not work and is hurting my child. I do not know what to use to get rid of the lice.

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
3 times

Therapy dates
4-03-03 to 4-24-03

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

I also used the Pronto spray. I sprayed her pillows.

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
1118	33/10/0	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 35/02/ **Date of report** 4/20/2003

Describe event or problem

cant get rid of lice HELP

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use

everyweek

Therapy dates

42002 to 41803

Diagnosis for use

all

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
1117	02/13/1998	female	50 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

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

other: Dry scalp and rash

Date of event 11/20/02 | **Date of report** 4/17/2003

Describe event or problem

I have used Nix and Rid to get rid of my child's lice, but about every 2-3 weeks, we keep finding more lice and nits. The first few times, I sprayed and washed everything in my house. I quit using the products when my daughter complained about her head still itching, and I found extremely dry scalp and a red rash. She's not even in school yet, so I can't imagine where she's getting them. I have always combed her hair thoroughly after I shampooed it with those products I listed, but the problem continued. I has calmed down now, and I check her head about every other day. If I find lice or nits, I still remove them with the metal comb, but I just can't use that shampoo anymore. Or, afford to use it. Any information will be greatly appreciated. Thank you for your time. CMelton.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
Approximately every 2 weeks.

Therapy dates
11/2002 to 01/2003

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

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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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
1114	01/06/1996	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: it burns my daughter's head

Date of event 04/14/2003 **Date of report** 4/15/2003

Describe event or problem

the medcine for the treatment of head lice burns my 7 year old daughters head

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Ovide

Dose, frequency, route use

0.5% i am using at least every 6 weeks

Therapy dates

6/10/02 to 04/14/03

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

no

Lot #

not known

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

rid 12/02/2002 lindane 03/31/03 mayo 12/30/02 vinegar every other day just about

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
1113	10/12/1968	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: lots of scars

Date of event 8/1/02 **Date of report** 4/12/2003

Describe event or problem

Iworked at a company one of the staff had a rash 8 weeks later I was all broke with my young children after about 2-3 weeks figured out it was scabies. Staff kept telling me it was birdlice when approached management I was fired for saying I need to consult a lawyer because she kept coming to work with new lesions and asking if I had more medicicne because other members in her family didn't treat.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
Permithin

Dose, frequency, route use
breakouts 7 days after

Therapy dates
7/1/02 to 4/12/03

Diagnosis for use
scabies

Event abated after use stopped or dose reduced
no

Lot #
Lindane

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
throughout this 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

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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
1112	08/02/1994	female	80 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: seizures

Date of event 11/04/2002 **Date of report** 4/12/2003

Describe event or problem

Child has suffered from seizures since using an OTC lice treatment. Also, prescription Elimite has done nothing for our problem.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

No preexisting medical contitions

C. Suspect medication(s)

Name: Nix
Rid

Dose, frequency, route use
once every three months

Therapy dates
11/2001 to 11/2003

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
nightly combing and picking through childs hair

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
1107	05-01-1984	female	165 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 03-01-03 **Date of report** 4/1/2003

Describe event or problem

we used lindane two different times and it didnt kill the big lice

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
twice

Therapy dates
03-01-03 to 03-31-03

Diagnosis for use
lice

Event abated after use stopped or dose reduced
no

Lot #
n/a

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
none other than using a lice comb

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
1100	02/11/1982	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: resistant lice

Date of event 00/00/0000 **Date of report** 3/23/2003

Describe event or problem

I have used over the counter treatments, such as NIX and RID. I have also gotten a prescription from my doctor for Lindane which I have also used several times and I can still not get rid of my head lice. I have had this case of head lice for about 6 months that is known. I dont know what to do to get rid of them. HELP!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I have no preexisting medical conditons. No illnesses.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

1% lindane shampoo

Therapy dates

02/06/03 to 00/00/0000

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

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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
1098	08/01/1996	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 03/20/03 **Date of report** 3/21/2003

Describe event or problem

I can not get the head lice out of my six year old. In return she keeps giving it to everybody in our house and I just don't understand why. The main problem now is the fact that they can not go to school because of it. What do I do

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
rid all of them

Dose, frequency, route use
once every 10 days

Therapy dates
01/2003 to 03/2003

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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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
1095	03/30/1994	male	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 10/30/02 **Date of report** 3/19/2003

Describe event or problem

This is our 4th outbreak in the last 6mo. Is there any end to this madness?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

he first 3 from the end of October to end of December. Finally got rid of it with Lindane, which I hated to use on my daughters. Is there a home remedy to treat head lice?

C. Suspect medication(s)

Name: Pronto

Nix, Rid, Kwell

Dose, frequency, route use

every 7-10 days

Therapy dates

10/30/02 to 12/31/02

Diagnosis for use

Tried all the above and Lindane.

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

I'd like an alternative method of treatment. I heard of a home treatment but do not know all the ingredients and amounts (olive oil, rosemary...)

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
1088	03/06/1996	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: Allergic/Intolerant Reaction to Pyrethrins

Date of event 19/99/2000 **Date of report** 3/8/2003

Describe event or problem

My daughter Heather has had intermittent problems with Head Lice ever since entering daycare. Initially, I tried a standard lice-killing shampoo, Licetrol, which did not have any marked effect on the lice. One week later, as instructed, I did a follow-up treatment on my daughters head and within an hour she had fallen to vomiting. At the time we didn't make the connection, but the next time we did because, sure enough, within half an hour of the second treatment she had fallen to vomiting again.

Needless to say I sought out medical information with regards to this from both our doctor and pharmacist, and was informed that in all likelyhood my daughter was either allergic/intolerant to pyrethrins, and was advised to seek and alternative treatment until she was old enough to use

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Now we're right back at the problems again. 18 months clean and then yesterday it turned up on my oldest daughter again. She seems to be particularly susceptible, and I suspect that that is a result of her having the same skin sensitivity that is passed on my father's side of the family. We are all allergic to perfumes and are unable to use skin creams, lotions, etc. Even soap is a difficulty.

C. Suspect medication(s)

Name: generic lice shampoo

Dose, frequency, route use

Just enough to lather hair with, twice at a one-week interval. Once in 1999 and

Therapy dates

1999 to 2000

Diagnosis for use

Unclear what this field is asking for.

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
1085	11/19/63	female	180 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 12-02 **Date of report** 2/28/2003

Describe event or problem

i have went to the public health clinic. the dr? insisted on giving me NIX which DOES NOT WORK!!!! I'VE BEEN FIGHTING THIS LICE PROBLEM SINCE DECEMBER. I AM DAMN NEAR SUICIDAL, THESE BUGS ARE RUINING MY LIFE, MY HAIR, MY CLOTHING. LINDANE DOES NOT WORK. I AM LOSING IT, I AM NERVOUS AND CRYING ALL THE TIME, THESE NITS ARE JUST GETTING THE BEST OF ME.
THE LICE HAVE GOT INTO MY EYES, TOO, SERIOUSLY. NO DOCTOR BELIEVES ME, I'M SERIOUS!!!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
LINDANE, ELIMITE

Dose, frequency, route use
EVERY OTHER DAY, I'M DESPERATE, AND CRYING

Therapy dates
1-25-03 to 3-1-03

Diagnosis for use
LINDANE, NIX, ELIMITE.

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
1082	1/14/97	female	38 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 10/01/02 **Date of report** 2/23/2003

Describe event or problem

prescribed Ovide for head lice and her scalp was very sore and irritated as were the scalps of her two brothers.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Head Lice have been a recurring problem for these children for over a year and nothing seems to work. The school keeps sending her home from kindergarten and she is failing.

C. Suspect medication(s)

Name: Ovide

Dose, frequency, route use
as needed

Therapy dates
10/01/02 to 10/14/02

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

NIX, Lice AWAy, Eckerds brand lice shampoos and too many others to recall since 2001

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

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MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
1081	01/26/1973	female	175 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 02/20/03 | **Date of report** 2/22/2003

Describe event or problem

My son came home with head lice from school back in November. Then my daughter and I both got it. I am not sure how unless from car seats although your site says otherwise. We don't share clothing, hats, coats, etc. Our couch is leather. Anyway, I have treated my daughter and son with multiple products (Clear, Rid, Wal-Mart's Equate) and not one of them work like they say they will. As a result, I have noticed that I have started losing hair and it breaks off. My hair comes out in handfulls and breaks off to the point that it looks as if I have taken scissors to it about an inch from my head. I just continually use the comb now on all of us. My hair is now so dry and brittle. Fortunately, I have really thick hair so it isn't noticeable but what if it continues?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Clear
Rid, Wal-Mart's Equate

Dose, frequency, route use	Therapy dates
According to directions on bottle every 10 days to 2 weeks	11/2002 to 2/10/03

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
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
1073	01/04/1990	female	70 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 02-2003 **Date of report** 2/6/2003

Describe event or problem

MY DAUGHTER IS NOW 13 YRS. OLD. WE HAVE BEEN BATTLING WITH LICE SINCE SHE WAS IN KINDERGARTEN. THAT WAS 8 YRS AGO. WE ARE STILL BATTLING WITH IT. FOR SOME REASON THE LICE WILL NOT LEAVE MY DAUGHTER ALONE. I HAVE TRIED EVERYTHING ON HER FROM RID TO PRESCRIPTION SHAMPOO FROM THE DOC. THAT WAS PURE POISON, TO CUTTING AND SHAVING HER HEAD TO MY FAMILY LIVING WITH PLASTIC COVERS ON EVERYTHING AND OUR BELONGINGS PLACED IN PLASTIC BAGS.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

TO ADD HEARTBREAK TO HEARTACHE MY HOUSEHOLD CONSISTS OF 5 TOTAL MEMBERS A CAT AND A DOG, TWO MEMBERS WITH EXTREMLY LONG THICK HAIR. THE ONLY PERSON TO CONTRACT THE BUG IS MY DAUGHTER. NO ONE ELSE HAS EVER HAD IT.

C. Suspect medication(s)

Name: Clear

Dose, frequency, route use
AS DIRECTED AND THEN SOME

Therapy dates
09-1994 to 02-2003

Diagnosis for use
DID NOT WORK

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

RID, NIX, PET LICE KILLING SHAMPOO, VINEGAR, BEER, HAIR BLEACH, PEANUT BUTTER, HOT HAIR DRIER, VEGTABLE OIL, SHAVING THE HEAD,

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
1071	05/31/1958	female	180 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 01/29/03 **Date of report** 2/3/2003

Describe event or problem

Have treated myself twice and still have problem. Have used Prescription and thrououghy combed my hair twice. Washed all pillows, bedding etc. This took hours!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
2 oz for 4 minutes
On 1/19 and 1/29

Therapy dates
1/19/2003 to 1/28/2003

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

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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
1068	05/15/95	female	41 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 07/20/01 | **Date of report** 1/30/2003

Describe event or problem

This has been an ongoing problem since July of 2001 With both of my daughters we have tried every product that is out there on the market. And it has been a year and a half and everything we have tried even picking all the eggs and nits out of the hair by hand. Has not helped they keep coming back.

We have tried all the treatments and has gone even as far as using olive oil. we even use the combs with the metal teeth to pull them out as well as with our fingers

Relevant tests/laboratory data

Other relevant history, including preexisting condition

The chemicals in the treatments keeps making me sick to my stomach. It has the same effects on both of my daughters

C. Suspect medication(s)

Name: Nix

we have tried them all

Dose, frequency, route use

We use these treatments once a week and when we can't afford them then it is

Therapy dates

7-2001 to 1-30-2003

Diagnosis for use

Doctors prescription and after that over the counter

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Don't know the lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

We have used all the medications and tried all the natural 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

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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
1062	02/05/1999	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: Complaining Eyes Hurt

Date of event 1/01/03 **Date of report** 1/22/2003

Describe event or problem

While I am not certain that my daughters problems are from the treatment, she has been complaining that her head hurts and her eyes. I will be taking her to a doctor to have this checked

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
RID Xta strength

Dose, frequency, route use
One bottle 3 to 4 different times

Therapy dates
11-29-02 to 01-01-03

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

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
1060	09/12/96	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: total reinfestation

Date of event 10/02-1/03 **Date of report** 1/18/2003

Describe event or problem

My children moved from Atlanta,GA to Lobelville,TN in October. They got head lice within 2 weeks.We began treating it immediately with over the counter products. We cleaned everything in our home. We spent hours on end picking nits and clipping hairs from their heads.When none of this worked we tried alternative treatments,found through the headlice.org website.It's now months later and we are still dealing with this problem.We have followed instructions right down to the letter time and time again.We have even gone as far as buy all new pillows and moving our beds out in the snow for 24 hours.We have bought the combs.We have tried the peppermint oils.We have used the salt water.We have used all the over the counter products.Our family doctor prescribed lindane.Nothing is working.I am in a panic.Someone is going to get their pants

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: lindane

Nix, Rid, Clear,Robicomb,generics,peppermint extr

Dose, frequency, route use	Therapy dates
Every week with follow up treatments every 10 days	10/02 to 01/03

Diagnosis for use

Mature lice and nits every time we retreat.

Event abated after use stopped or dose reduced

no

Lot #	Exp. date
n/a	

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
1058	12/22/1993	male	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: still finding lice

Date of event 1/9/2002 **Date of report** 1/10/2003

Describe event or problem

Still seeing live lice after treatment and cleaning.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
?

Therapy dates
1/6/03 to 1/6/03

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

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

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

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