

IN THE MATTER OF

DEL PHARMACEUTICALS, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3837. Complaint, Dec. 8, 1998--Decision, Dec. 8, 1998*

This consent order prohibits, among other things, two New York-based pharmaceutical companies from making unsubstantiated claims concerning the efficacy of their over-the-counter head lice treatments. The consent order requires the respondents to make certain disclosures in advertisements concerning the use and effectiveness of their head lice treatment products. In addition, the consent order prohibits the respondents from making claims about the extent to which health care, child care, or other medical professionals recommend Baby Orajel, or any other topically applied oral cleanser, unless the respondents have adequate substantiation to support their claims.

Participants

For the Commission: *Linda Badger, Kerry O'Brien, Jeffrey Klurfeld, and Carolyn Cox.*

For the respondents: *Nancy Buc and Philip Katz, Buc & Beardsley, Washington, D.C.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Del Pharmaceuticals, Inc. and Del Laboratories, Inc., corporations ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Del Pharmaceuticals, Inc. is a Delaware corporation with its principal office or place of business at 178 EAB Plaza, Uniondale, New York. Del Pharmaceuticals is a wholly-owned subsidiary of Del Laboratories, Inc.
2. Respondent Del Laboratories, Inc. is a Delaware corporation with its principal office or place of business at 178 EAB Plaza, Uniondale, New York.
3. Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed cosmetics and over-the-counter pharmaceuticals to the public, including "Pronto Lice Treatment" and

"Baby Orajel Tooth & Gum Cleanser." Pronto Lice Treatment is a pediculicide, which contains the active ingredients of 0.33 percent pyrethrum extract and 4 percent piperonyl butoxide. Baby Orajel Tooth & Gum Cleanser is a topically applied oral cleansing product, which is designed to clean the teeth and gums of infants and toddlers. Pronto Lice Treatment is a "drug" and Baby Orajel Tooth & Gum Cleanser is a "drug" and/or "cosmetic" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

4. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

PRONTO LICE TREATMENT

5. Respondents have disseminated or have caused to be disseminated advertisements for Pronto Lice Treatment, including but not necessarily limited to the attached Exhibits A through G. These advertisements contain the following statements:

A. "100% Effective In Laboratory Testing In Killing Lice And Eggs. 0% Lasting Chemical Pesticide Residue Left in Your Child's Hair. Only One Lice Treatment Can Make These Claims.

...
Pronto is the only lice shampoo that's laboratory-tested 100% effective in killing lice and eggs*...Plus Pronto actually helps prevent reinfestation. Breakthrough Formula Pronto. 100% effective in laboratory testing in killing lice and their eggs. While leaving nothing behind but clean, healthy hair.

...
*Data on file. Use as directed." (Exhibit A).

B. "What parents should know about head lice infestations.

Fallacy & Fact

...
Fact
While it's true that all lice killing shampoos can kill adult lice, they don't all have the same effectiveness in killing lice eggs (nits) which can hatch later and cause reinfestation. Pronto Shampoo-and-Conditioner-in-One is laboratory proven to kill ALL lice and eggs." (Exhibit B).

C. "... brought to you by Pronto

The only lice shampoo laboratory tested 100% effective in killing lice and eggs without leaving a lasting pesticide residue. Pronto. So your child's hair is clean and healthy." (Exhibit C).

D. "Announcer: Raulito is not going to school today because his mother found out he has lice.

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Teacher: There isn't a better treatment than Pronto shampoo. It's the only one 100% effective against lice and eggs without leaving a lasting pesticide residue. Laboratory test show that it's more effective than Rid. Pronto is so effective that it guarantees it or your money back. Use Pronto! There is nothing more effective against lice.

Student (Raulito): And dead lice!"

(Exhibit D, translated from Spanish).

E. "Kills all the lice and their nits on contact."

(Exhibit E, translated from Spanish).

F. "Get Lice Out of Your Hair and Home!

Fast Acting Pronto

Lice Killing Shampoo Kit

One Treatment Kills Lice & Their Eggs on Contact."

(Exhibit F).

G. "Medical Update for Pharmacists.

...

Recommend Breakthrough Formula Pronto

Pronto represents a true breakthrough in pediculicide efficacy.

Pronto is Laboratory-Tested 100% Effective in Killing Lice and Eggs

Pronto is the first and only lice shampoo proven in single treatment laboratory tests to be 100% effective in killing lice and eggs."

(Exhibit G).

6. Through the means described in paragraph five, respondents have represented, expressly or by implication, that:

A. Pronto Lice Treatment kills one hundred percent of lice eggs.

B. Pronto Lice Treatment is one hundred percent effective in killing lice and their eggs in a single treatment.

C. Pronto Lice Treatment helps prevent reinfestation.

7. In truth and in fact:

A. Pronto Lice Treatment does not kill one hundred percent of lice eggs. Pronto Lice Treatment is based on a pesticide which is not one hundred percent effective against lice eggs. As a result, purchasers are provided with an egg-removing comb, and are instructed to apply a second treatment in seven to ten days to kill any newly hatched lice.

B. Pronto Lice Treatment is not one hundred percent effective in killing lice and their eggs in a single treatment. In most cases, it must be reapplied in seven to ten days.

C. In many cases, Pronto Lice Treatment does not help prevent reinfestation. It does not leave a lasting pesticidal residue that would help prevent reinfestation from post-treatment contacts with other lice-infested people or things.

Therefore, the representations set forth in paragraph six were, and are, false or misleading.

8. Through the means described in paragraph five, respondents have represented, expressly or by implication, that laboratory tests prove that Pronto Lice Treatment is one hundred percent effective in killing lice and their eggs.

9. In truth and in fact, laboratory tests do not prove that Pronto Lice Treatment is one hundred percent effective in killing lice and their eggs. Therefore, the representation set forth in paragraph eight was, and is, false or misleading.

10. Through the means described in paragraph five, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in paragraph six, at the time the representations were made.

11. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in paragraph six, at the time the representations were made. Therefore, the representation set forth in paragraph ten was, and is, false or misleading.

BABY ORAJEL TOOTH & GUM CLEANSER

12. Respondents have disseminated or have caused to be disseminated advertisements for Baby Orajel Tooth & Gum Cleanser, including but not necessarily limited to the attached Exhibits H and I. These advertisements contain the following statements:

A. "Baby teeth have special needs.

Pediatricians recommend Baby Orajel Tooth & Gum Cleanser.

...

• Pediatrician recommended.

Nine out of every ten pediatricians surveyed would recommend Baby Orajel Tooth & Gum Cleanser." (Exhibit H)

B. "Ordinary toothpastes are great for older kids, but baby teeth have special needs.

Discover why pediatricians recommend Baby Orajel Tooth & Gum Cleanser.

...

- **PEDIATRICIAN RECOMMENDED.**

Nine out of every ten pediatricians surveyed would recommend Baby Orajel Tooth & Gum Cleanser." (Exhibit I)

13. Through the means described in paragraph twelve, respondents have represented, expressly or by implication, that competent and reliable surveys show that nine out of ten pediatricians would recommend Baby Orajel Tooth & Gum Cleanser.

14. In truth and in fact, competent and reliable surveys do not show that nine out of ten pediatricians surveyed would recommend Baby Orajel Tooth & Gum Cleanser. Among other reasons, the survey relied upon by respondents is methodologically flawed and the greatest number of respondents to that survey said they were only "somewhat likely" to recommend Baby Orajel Tooth & Gum Cleanser. Therefore, the representation set forth in paragraph thirteen was, and is, false or misleading.

15. Through the means described in paragraph twelve, respondents have represented, expressly or by implication, that nine out of ten pediatricians recommend Baby Orajel Tooth & Gum Cleanser.

16. Through the means described in paragraph twelve, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in paragraphs thirteen and fifteen, at the time the representations were made.

17. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in paragraphs thirteen and fifteen, at the time the representations were made. In addition to the reasons stated in paragraph fourteen, the survey relied upon by respondents was not designed to elicit whether pediatricians actually do recommend Baby Orajel Tooth & Gum Cleanser to their patients. The survey merely asked pediatricians how likely they would be to recommend the product. Therefore, the representation set forth in paragraph sixteen was, and is, false or misleading.

18. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

Complaint

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EXHIBIT A

**100% Effective In
Laboratory Testing
In Killing Lice And Eggs.**

**0% Lasting Chemical Pesticide Residue
Left In Your Child's Hair.**

**Only One Lice Treatment Can
Make These Claims.**

...ent there is. But you don't
... residue. That's why the only lice
... and 100% effective in killing lice and eggs.*
... works without leaving a lasting pesticide
... prevent reinfestation.
... in laboratory testing in killing lice and their
... clean, healthy hair.

Breakthrough Formula Pronto.®

EXHIBIT A

Data on file. Use as directed. ©1996 Del Pharmaceuticals, Inc. a subsidiary of Del Laboratories, Inc.



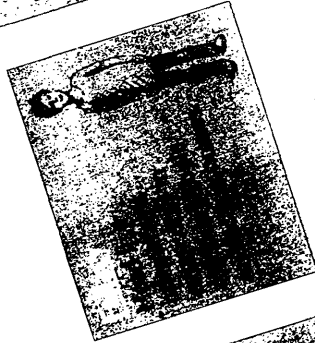
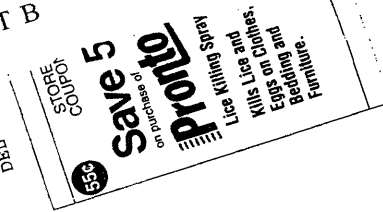
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DEL PHARMACEUTICALS, INC., ET AL.

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EXHIBIT B

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Fact
Lice infestation is a common problem for many children. It is not a sign of poor hygiene or poverty. Lice can be found on children of all ages, races, and social classes. The only way to get rid of lice is by using a proven lice treatment.

Fact
Millions of American children become infested with head lice each year, regardless of race, age, or social class. Head lice do not discriminate by sex, race, or economic status. However, they are most often found on school-age children. American children have a much higher incidence of infestation than children in other countries.

Fallacy & Fact
There are many fallacies about head lice. This booklet will give you the facts about these tiny parasites and tell you the best ways to eliminate them when your child becomes infested. A lice infestation is usually suspected by itching and scratching of the head and back of the neck, or by finding especially the back of the head and ears. It is usually confirmed by finding yellowish-white eggs (nits) near the scalp.

An Educational Service from the National Association of Del Pharmaceu...
of 'pronto' Lice Killing...
Condition...
Del Pharmaceu...
a subsidiary of Del Laboratories, Inc.
163 East...
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Complaint

126 F.T.C.

EXHIBIT B

**Fact**

While it's true that all lice killing shampoos can kill adult lice, they don't all have the same effectiveness in killing lice eggs (nits) which can hatch later and cause reinestation. Pronto Shampoo-and-Conditioner-in-One is laboratory proven to kill ALL lice and eggs. What's more, its maximum strength pyrethrin formula will not leave a lasting pesticide residue on the child's head, like the leading creme rinse lice product that contains the synthetic ingredient permethrin.

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DEL**Fact**

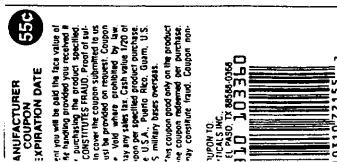
To prevent reinestation, there are other precautions you should take:

1. All clothing and bed linens that have been in contact with the infested person must be washed in hot water and dried in a hot dryer.
2. Combs and brushes should be discarded or soaked in a lice shampoo for one hour.
3. Vacuum all rugs, furniture, and mattresses. You may want to use Pronto lice killing spray.

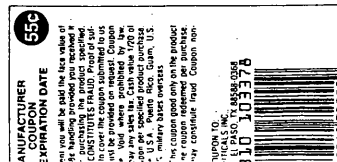
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DEL**Fact**

The head louse cannot jump, hop or fly. And it is a human parasite that cannot live on the body of a dog or cat. The only way people become infested is through direct contact with infested persons, or by wearing infested clothing, using infested combs or brushes, or lying on infested bedding, carpeting or furniture. It's important that you caution your children about sharing a playmate's hat, clothing, or comb.

EXHIBIT B-1

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EXHIBIT C

Minimercial Copy

... brought to you by Pronto

The only lice shampoo laboratory tested 100% effective in killing lice and eggs without leaving a lasting pesticide residue. Pronto. So your child's hair is clean and healthy.

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DEL

EXHIBIT D

PRONTO

"RAULITO" :30

Spanish

Locutor: Raulito no va a la escuela porque su mama entero que tiene piojos.

Maestra: No hay mejor tratamiento que el champú Pronto. El único cien por ciento efectivo contra piojos y huevecillos sin dejar residuos de pesticida duraderos. Pruebas de laboratorio demuestran que es más efectivo que Rid.

Pronto es tan efectivo que lo garantiza o le devuelva su dinero.

¡Use Pronto! No hay nada mas efectivo contra piojos.

Estudiante (Raulito): ¡Y muerta piojos!

English

Announcer: Raulito is not going to school today because his mother found out he has lice.

Teacher: There isn't a better treatment than Pronto shampoo. It's the only one 100% effective against lice and eggs without leaving a lasting pesticide residue. Laboratory test show that it's more effective than Rid.

Pronto is so effective that it guarantees it or your money back.

Use Pronto! There is nothing more effective against lice.

Student (Raulito): And dead lice!

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EXHIBIT D

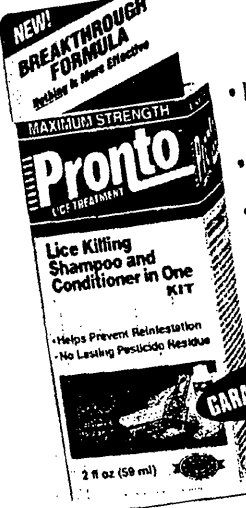
Complaint

EXHIBIT E

Print ad

¿Problemas de Piojos?

¡Resuélvalo Pronto!



- Llegó Pronto® Champú y Acondicionador
- Nueva fórmula
- Mata todos los piojos y sus liendres al contacto
- Ayuda a prevenir el contagio
- Sin residuos pesticidas

GARANTIZADO

Pídalo en su Farmacia Favorita

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EXHIBIT E

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Complaint

EXHIBIT F

The advertisement is divided into two main sections. The top section promotes the 'Pronto' lice killing system, featuring a box labeled 'Pronto LICE KILLING SHAMPOO KIT' and a bottle of 'Pronto' spray. The text reads: 'Use the Pronto® LICE KILLING SYSTEM'. The bottom section promotes Walgreens' prescription services, featuring the Walgreens logo and the text 'The Prescription Center'. Below this, it says 'Yours For The Asking' and provides information about child-resistant containers. At the bottom, it shows three prescription bottles with labels: 'PILAZITHE 5', 'LOPEXAZONE, N', and 'LOPEXAZONE, N'. The Walgreens logo and 'Your Intercom Pharmacy' are at the very bottom.

Pronto
LICE KILLING SHAMPOO KIT

Use the
Pronto®
LICE KILLING SYSTEM

Walgreens The Prescription Center

Yours For The Asking

While most prescriptions are dispensed in child-resistant containers, the regular (non-safety caps) are available upon request.

The Choice Is Yours!

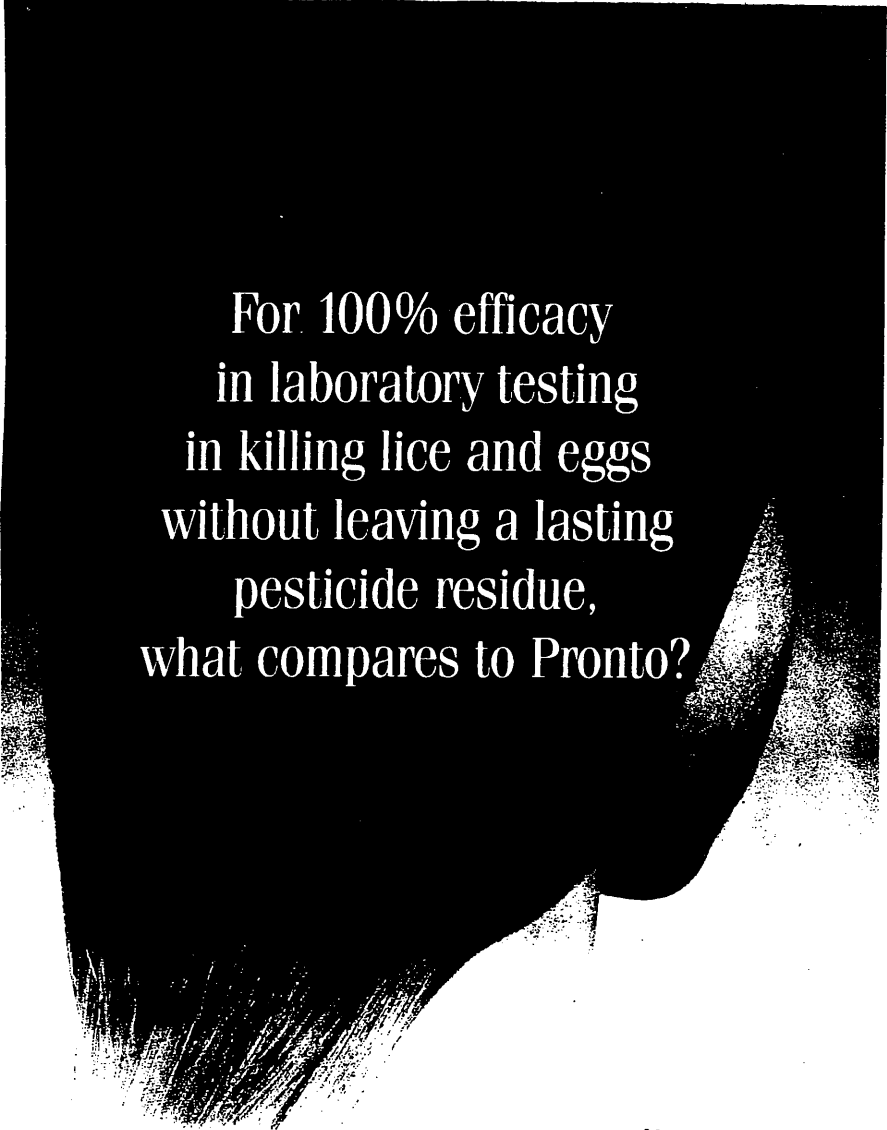
PILAZITHE 5
NEXA
20337-60
703794-8 BCM

LOPEXAZONE, N
NEXA
20337-60
703794-8 BCM

Walgreens Your Intercom Pharmacy

EX. F

EXHIBIT G



For 100% efficacy
in laboratory testing
in killing lice and eggs
without leaving a lasting
pesticide residue,
what compares to Pronto?

EXHIBIT G

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EXHIBIT G

**Recommend the Most Effective Treatment**

When someone's child has lice, you want to recommend the most effective treatment there is. Combine the improved formula with other Pronto benefits, and nothing compares to Pronto.

Recommend Breakthrough Formula Pronto

Pronto represents a true breakthrough in pediculicide efficacy.

Pronto is Laboratory-Tested 100% Effective in Killing Lice and Eggs

Pronto is the first and only lice shampoo proven in single treatment laboratory tests to be 100% effective in killing lice and eggs.

Pronto Works Without Leaving a Lasting Pesticide Residue

Unlike the leading creme rinse treatment, Pronto leaves nothing behind but clean, healthy hair. Plus, it actually helps prevent reinfestation.

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EXHIBIT G-1

EXHIBIT H

EXHIBIT H

Baby teeth have special needs.

Pediatricians recommend Baby Orajel® Tooth & Gum Cleanser.

- **Kids get plaque, too.**
Sugars in formula, juice, and other foods form plaque. Water isn't enough to remove it. And ordinary toothpaste has disadvantages.
- **Unique plaque-fighter for babies and toddlers.**
Gentle Microdent™ helps remove plaque from soft new teeth and prevent its build-up.
- **Non-abrasive and fluoride-free.**
It's gentle on new enamel and gums. Also, ask your doctor why fluoride toothpaste may not be right for your baby.
- **Non-foaming and safe to swallow.**
That's important since young children have trouble spitting out.
- **Babies and toddlers love the taste.**
Now good oral hygiene can be fun!
- **Pediatrician recommended.**
Nine out of every ten pediatricians surveyed would recommend Baby Orajel® Tooth & Gum Cleanser. Ask your doctor.



The one for kids under four.

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Complaint

EXHIBIT I

EXHIBIT I

Ordinary toothpastes
are great for older kids,
but baby teeth have
special needs.



1 year

Discover why pediatricians recommend
Baby Orajel® Tooth & Gum Cleanser.

KIDS GET PLAQUE, TOO.

Sugars in formula, juice and other foods form plaque. Water isn't enough to remove it. And ordinary toothpaste has disadvantages.

UNIQUE PLAQUE-FIGHTER FOR BABIES AND TODDLERS.

Gentle Microdent® helps remove plaque from soft new teeth and prevent its build-up.

NON-ABRASIVE AND FLUORIDE-FREE.

It's gentle on new enamel and gums. Also, ask your doctor why fluoride toothpaste may not be right for your baby.

NON-FOAMING AND SAFE TO SWALLOW.

That's important since young children have trouble spitting out.

BABIES AND TODDLERS LOVE THE TASTE.

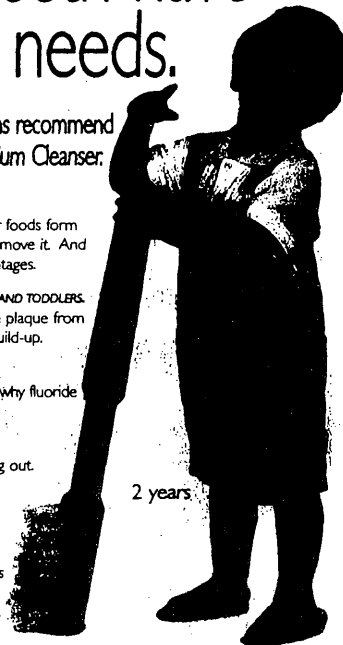
Now good oral hygiene can be fun!

PEDIATRICIAN RECOMMENDED.

Nine out of every ten pediatricians surveyed would recommend Baby Orajel Tooth & Gum Cleanser.



3 years



2 years

The one
for kids
under
four.



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For more information and coupons, call 1-800-952-5090 or visit us at www.orajel.com

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the San Francisco Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents, their attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1.a. Respondent Del Pharmaceuticals, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 178 EAB Plaza, Uniondale, New York. Del Pharmaceuticals is a wholly-owned subsidiary of Del Laboratories, Inc.

1.b. Respondent Del Laboratories, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 178 EAB Plaza, Uniondale, New York.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. "*Competent and reliable scientific evidence*" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

2. "*Pronto Lice Treatment*" shall mean the pediculicide marketed by respondents which contains the active ingredients of 0.33 percent pyrethrum extract and 4 percent piperonyl butoxide.

3. "*Substantially similar product*" shall mean any pediculicide marketed by respondents which contains the active ingredients of pyrethrum extract and piperonyl butoxide, and is covered by the Food and Drug Administration's Final Monograph on OTC Pediculicide Drug Products.

4. "*Baby Orajel Tooth & Gum Cleanser*" shall mean the topical oral treatment for infants and toddlers marketed by respondents that contains the active ingredient Microdent™ (Poloxamer 407 2.0%, Simethicone 0.12%).

5. Unless otherwise specified, "*respondents*" shall mean Del Pharmaceuticals, Inc. and Del Laboratories, Inc., corporations, their successors and assigns, and their officers, agents, representatives, and employees.

6. "*Commerce*" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. 44.

7. "*Drug*" and "*device*" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. 55.

8. "*Pesticide*" shall mean as defined in Section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136(u).

9. "*Clearly and prominently*" shall mean as follows:

A. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet and online services), any audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. Any video disclosure shall be of a size and shade, and shall appear on the screen for a duration,

sufficient for an ordinary consumer to read and comprehend it. In addition to the foregoing, in interactive media the disclosure shall also be unavoidable and shall be presented prior to the consumer incurring any financial obligation.

B. In a print advertisement or promotional material, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears. In multipage documents, the disclosure shall appear on the cover or first page.

Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label.

I.

It is ordered, That respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Pronto Lice Treatment or any substantially similar product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that:

- A. Such product kills one hundred percent of lice eggs;
- B. Such product is one hundred percent effective in killing lice and their eggs in a single treatment; or
- C. Such product prevents reinfestation,

unless the representation is true and, at the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

It is further ordered, That, for a period of two (2) years from the date of service of this order, respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Pronto Lice Treatment or any other substantially similar product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, in print advertisements or promotional materials about the efficacy of such product in the removal or elimination of lice or the treatment of lice infestations ("triggering representation"), unless it makes the

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Decision and Order

following disclosure, clearly and prominently, in such advertisements or promotional materials containing the triggering representation:

Reapplication and egg removal are required to ensure complete effectiveness.
See label for important information.

Provided, however, that the above disclosure shall not be required if respondents possess and rely upon competent and reliable scientific evidence demonstrating that the product is effective for the complete elimination of all lice and lice eggs in a single application.

Provided, further, that the above disclosure shall not be required in a particular piece of promotional material if such promotional material constitutes "labeling of a pediculicide drug product" subject to the labeling requirements of the Food and Drug Administration's Final Monograph on OTC Pediculicide Drug Products, 21 CFR 358.650.

III.

It is further ordered, That, for a period of two (2) years from the date of service of this order, respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Pronto Lice Treatment or any other substantially similar product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, in advertisements communicated through an electronic medium, about the efficacy of such product in the removal or elimination of lice or the treatment of lice infestations ("triggering representation"), unless it makes the following disclosure, clearly and prominently, in the video portion of such advertisements (or in the audio portion if the advertisement is audio only) containing the triggering representation:

Two Treatments Required.

Provided, however, that if the respondents make any representation, in any manner, expressly or by implication, about directions for use of such product in advertisements communicated through an electronic medium utilizing both video and audio, the disclosure shall be presented in both the video and the audio portions of such advertisements.

Provided, further, that the above disclosure shall not be required if respondents possess and rely upon competent and reliable scientific evidence demonstrating that the product is effective for the complete elimination of all lice and lice eggs in a single application.

IV.

It is further ordered, That respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Baby Orajel Tooth & Gum Cleanser or any other topically applied oral cleansing product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about:

A. The extent to which doctors or other health, childcare, or medical professionals recommend or would recommend such product; or

B. The recommendation, approval, or endorsement of such product by any health, childcare, or medical professional, profession, group or other entity;

unless, at the time the representation is made, respondents possess and rely upon competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence, that substantiates the representation.

V.

It is further ordered, That respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any drug or device for the treatment of lice in humans, any pesticide for treatment of lice, or any topically applied oral cleansing product in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

VI.

It is further ordered, That respondents, directly or through any corporation, subsidiary, division, or other device, in connection with

the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any drug or device for the treatment of lice in humans, or any pesticide for treatment of lice in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, regarding the efficacy of such product, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

VII.

It is further ordered, That the Parts I, II, III, V and VI of this order shall not apply to any labels or labeling printed prior to the date that the explanation of this order is published in the Federal Register for public comment pursuant to Section 2.34 of the Commission's Rules and shipped by respondents prior to one hundred (100) days after the date that the explanation of this order is published in the Federal Register for public comment pursuant to Section 2.34 of the Commission's Rules.

VIII.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in the labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

IX.

It is further ordered, That respondents Del Pharmaceuticals, Inc. and Del Laboratories, Inc., and their successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call

into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

X.

It is further ordered, That respondents Del Pharmaceuticals, Inc. and Del Laboratories, Inc., and their successors and assigns shall deliver a copy of this order to all current and future principals, officers, and directors, and to all current and future managers, employees, agents, and representatives having responsibilities with respect to the subject matter of this order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and, for a period of five (5) years from the date of issuance of this order, to future personnel within thirty (30) days after the person assumes such position or responsibilities.

XI.

It is further ordered, That respondents Del Pharmaceuticals, Inc. and Del Laboratories, Inc., and their successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondents learn less than thirty (30) days prior to the date such action is to take place, respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C.

XII.

It is further ordered, That respondents Del Pharmaceuticals, Inc. and Del Laboratories, Inc., and their successors and assigns shall, within sixty (60) days after the date of service of this order, and at

such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XIII.

This order will terminate on December 8, 2018, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondents did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

STATEMENT OF CHAIRMAN PITOFSKY AND COMMISSIONERS ANTHONY AND THOMPSON

We write to express our views about the concerns Commissioner Swindle raises regarding the disclosure remedy in these cases. The orders require that, for two years, whenever a claim is made regarding the efficacy of the lice removal products, the respondents include a disclosure about the necessity for a second application of their product. The disclosure remedy in these cases is fencing-in relief, designed to prevent purchasers of respondents' products from being deceived by *future* advertising.¹ The triggered disclosure about the

¹ It is also worth noting that the Commission has distinguished triggered disclosures such as those in these cases from corrective advertising, which is required regardless of the contents of the ad. *Removatron Int'l Corp.*, 111 FTC 206, 311-12 n. 28 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989). See also *American Home Prods. Corp. v. FTC*, 695 F.2d 681, 700 (3rd Cir. 1982).

need for two treatments provides additional assurance that consumers will not be misled by future ads. We are satisfied that the triggered disclosures in these orders are appropriate and reasonable.

STATEMENT OF COMMISSIONER ORSON SWINDLE

I have voted in favor of issuance of the final orders in these cases because there is reason to believe that the respondents have violated the law and most of the relief contained in the orders is necessary and appropriate. However, I continue to have concerns with regard to the need for and scope of one of the disclosure requirements contained in the orders.

The complaints include the allegation that the respondents claimed that their respective lice products eradicate a lice infestation after a single treatment. In truth, reapplication and careful combing are required to complete the treatments. To address this allegedly false claim, the orders prohibit the respondents from making, expressly or by implication, any claim that their lice treatment products work in only one treatment, unless that claim is true and substantiated. I agree that this prohibition is necessary and appropriate.

The orders, however, go further. For a period of two years, whenever the respondents make any efficacy claim for one of their lice treatment products, they must disclose "Two Treatments Required." The majority of the Commission has cast this provision as a "triggered disclosure requirement" and concluded that it is "appropriate and reasonably related to the alleged violations of Section 5." Even if this is a triggered disclosure requirement,¹ I do not believe that it is either necessary or appropriate.

The majority apparently believes that consumers will be misled if the respondents do not disclose that two treatments are required whenever they make an efficacy claim for their products. However, if a respondent makes a one-treatment claim that is false or unsubstantiated, the Commission can bring an action for violating the

¹ The majority is correct that the requirement has the form of a triggered disclosure, but the substance of the requirement is indistinguishable from corrective advertising. The disclosure will be required whenever the respondents make any express or implied claim that their products are efficacious, which likely would include all or virtually all of the ads they run for their lice treatment products. The disclosure also is required for only a limited period of time, which is also consistent with being a corrective advertising measure.

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Statement

injunctive provisions of the order, and thus the two-treatment disclosure requirement would be unnecessary. On the other hand, if a respondent makes a one-treatment claim that is true and substantiated, the disclosure itself -- "Two Treatments Required" -- would be false, because the product would require only one treatment to be effective. Consequently, the disclosure requirement is not needed to prevent the respondents from making the misleading claim that their lice products work in one treatment.

Even if some sort of disclosure requirement were needed to prevent deception, the disclosure requirement imposed here is not appropriate. It appears both overbroad and inadequate in duration. The triggered disclosure must be made whenever an efficacy claim is made, but not every efficacy claim (*e.g.*, the product "works") creates the impression that the product will work in only one treatment. Without such an impression, there may well be no need to disclose that two treatments are required. Moreover, the triggered disclosure requirement is inadequate because it terminates after two years. If the disclosure in fact is necessary to prevent deception, then why does it end after two years? If the Commission decides to impose a triggered disclosure requirement to prevent future ads from being deceptive, it should be triggered by a claim that would be deceptive in the absence of the information to be disclosed and should continue as long as necessary to prevent deception.

I support the Commission's move toward stronger remedies. The injunctive provisions of these orders, together with the FDA-mandated labeling,² should ensure that consumers have truthful and accurate information before and after purchase. The disclosure requirement here, however, is unnecessary and inappropriate.

² The FDA requires the following statement on the label of any shampoo formulated to treat head lice: "Apply to affected area until all the hair is thoroughly wet with product. Allow product to remain on area for 10 minutes but no longer. Add sufficient warm water to form a lather and shampoo as usual. Rinse thoroughly. A fine-toothed comb or special lice/nit removing comb may be used to help remove dead lice or their eggs (nits) from hair. A second treatment must be done in 7 to 10 days to kill any newly hatched lice."

IN THE MATTER OF

ALBERTSON'S, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT

Docket C-3838. Complaint, Dec. 8, 1998--Decision, Dec. 8, 1998

This consent order, among other things, requires the respondents to divest 15 supermarkets, eight in Montana and seven in Wyoming. In addition, the consent order requires the respondents to provide written notification to the Commission prior to acquiring any facility that has operated as a supermarket in the designated areas.

Participants

For the Commission: *James Fishkin, Joseph Brownman, Phillip Broyles, William Baer, William Layher, and Jonathan Baker.*

For the respondents: *Christopher MacAvoy, Collier, Shannon, Rill & Scott, Washington, D.C. and Henry Thumann, O'Melveny & Myers, Los Angeles, CA.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that respondent Albertson's, Inc. ("Albertson's") and respondent Locomotive Acquisition Corporation ("Locomotive"), a wholly-owned subsidiary of respondent Albertson's, have entered into an agreement to acquire all of the outstanding shares of respondent Buttrey Food and Drug Store Company, Inc. ("Buttrey"), a corporation of which a majority of the voting securities is owned by respondent FS Equity Partners II, L.P. ("FS Equity Partners"), all subject to the jurisdiction of the Commission, in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, and that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows: