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17/2

JUN 22 1993

Dr. Harry Gordon
DEL Pharmaceuticals, Inc.
565 Broad Hollow Road
Farmingdale, NY 11735

Dear Dr. Gordon:

Subject: Updated Labeling
Barc Liquid
EPA Registration No. 2398-4
Your Submission Dated January 20, 1993

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, provided that you make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

(Note: All comments apply to both bottle label copy and carton label copy).

1. Delete "this and all drugs" so that the statement reads "Keep out of reach of children."
2. Revise Precautionary Statements as follows:

"For external use only. Harmful if swallowed. Do not inhale. Do not use near the eyes or permit contact with mucous membranes. If product gets into the eyes, immediately flush with water. Consult a physician if infestation of eyebrows and eyelashes occurs. If skin irritation or infection is present or develops, discontinue use and consult a physician. Avoid contamination of feed or foodstuffs."
3. The signal word for your product is CAUTION. It is the only signal word which may appear on your labeling. Therefore revise the statement to read "CAUTION: Not to be used by persons allergic to ragweed."
4. Preface crab lice with pubic everywhere it appears on the labeling. For example: "Kills head lice, pubic (crab) lice and their eggs on contact."

CONCURRENCES

SYMBOL							
SURNAME	Wheeler						
DATE	6-17-93						

- 5. Include statements (e)(1) Head Lice and (e)(2) Pubic (Crab) Lice from page 13488 (enclosed) of the Food and Drug Administration's Tentative Final Monograph for Over-the-Counter Pediculicide Drug Products. A complete copy of the monograph was enclosed with our September 30, 1992 letter.

Submit three copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

Sincerely,

George T. LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure

Carton Copy (6 point or larger, signal word in 10 point)

Send on draft labelling dated 9/24/92

384

Front Panel

Barc^R Liquid (logo)
A pediculicide
One application kills head lice crab lice and their eggs on contact
Special hair comb inside package

CAUTION: Keep this and all drugs out of reach of children. See side and back panels for additional precautions.
For external use only.

2 fl oz (59 ml)

Top Panel

Barc^R Liquid (logo)
Kills head lice, crab lice and their eggs on contact

Left Side Panel

Barc (logo) liquid
with special hair comb inside package

Right Side Panel

DIRECTIONS: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply sufficiently to completely saturate the hair and scalp or skin of any infested area. Allow application to remain no longer than 10 minutes. Wash and rinse thoroughly with plenty of warm water. While still damp, comb hair with a fine comb to remove dead lice and eggs from hair. To restore body and luster to the hair, use a good shampoo. Use no more than 2 times in 24 hours. A second treatment must be made in 7 to 10 days to kill any newly hatched lice.

ACTIVE INGREDIENTS:

Pyrethrins.....0.18%
*Piperonyl Butoxide Technical....2.20%
**Inert Ingredients.....97.62%
Total.....100.00%

*Equivalent to 1.78% (Butylcarbityl), (6-Propylpiperonyl) ether and 0.44% related compounds.

**Contains petroleum distillate

EPA Est. 2398-NY-1

EPA Reg. No. 2398-4

Back Panel

Barc^R Liquid (logo)
Kills head lice, crab lice and their eggs on contact

WARNING: Not to be used by persons allergic to ragweed.

PRECAUTIONARY STATEMENT: Hazard to Humans and Domestic Animals.

CAUTION: Keep this and all drugs out of the reach of children. Do not inhale. Harmful if swallowed. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Do not use near eyes or permit contact with mucous membranes. If product should get into eyes, immediately flush with plenty of clear water. In order to prevent reinfestation with lice, all clothing and bedding must be sterilized or treated concurrent with the application of this preparation. If skin irritation or signs of infection are present, consult a physician.

(Note: the following section should be in a box)

STORAGE AND DISPOSAL

Store at room temperature (15-30 °C, 59-86 °F) away from heat or open flame.

Do not reuse empty container. Wrap container and put in trash.

(c)Del Pharmaceuticals, Inc., a subsidiary of Del Laboratories, Inc.

565 Broad Hollow Road, Farmingdale, NY 11735

Made in U.S.A. 347014002 (component number)

7014

Bottom Panel

UPC Code # 3-10310-22803-3

ACCEPTED
with COMMENTS
in EPA Letter Dated

JUN 22 1993

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

2398-4

Label Copy (8 point or larger)

4 3 4

Front Label

Baro[®] Liquid (logo)

A pediculicide

Kills lice and their eggs on contact

ACTIVE INGREDIENTS:

Pyrethrins.....	0.18%
*Piperonyl Butoxide Technical....	2.20%
**Inert Ingredients.....	97.62%
Total.....	100.00%

*Equivalent to 1.76% (Butylcarbityl), (6-Propylpiperonyl) ether and 0.44% related compound.

**Contains petroleum distillate

For external use only. **CAUTION: Keep this and all drugs out of the reach of children. See back panel for additional precautions.**

2 fl oz (59 ml)

Del Pharmaceuticals, Inc., a subsidiary of Del Laboratories, Inc.
 5 Broad Hollow Road, Farmingdale, NY 11735
 Made in U.S.A. 217014002 (component number)

Back Label

DIRECTIONS: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply sufficiently to completely saturate the hair and scalp or skin of any infested area. Allow application to remain no longer than 10 minutes. Wash and rinse thoroughly with plenty of warm water. While still damp, comb hair with a fine comb to remove dead lice and eggs from hair. To restore brightness and luster to the hair, use a good shampoo. Use no more than 2 times in 24 hours. A second treatment must be made in 7 to 10 days to kill any newly hatched lice.

WARNING: Not to be used by persons allergic to ragweed.

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CAUTION: Keep this and all drugs out of the reach of children. Do not inhale. Harmful if swallowed. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Do not use near eyes or permit contact with mucous membranes. If product should get into eyes, immediately flush with plenty of clear water. In order to prevent reinfestation with lice, all clothing and bedding must be sterilized or treated concurrent with the application of this preparation. If skin irritation or signs of infection are present, consult a physician.

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