

Best copy available

36864-1

01/24/1996

1/4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



JAN 1996

300/5499175
315-495-243
13/13
17/14

Ms. Marcie Behan
Pierson Laboratories, Inc.
PO Box 157
Saluda, NC 28773

Dear Ms. Behan:

Subject: Amendment - Label Design Changes/Add Manufactured; New Confidential Statement of Formula (CSF) Chigg Away
EPA Registration No. 36864-1
Your Application Dated May 2, 1995 and Letter FAXed January 16, 1996

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 change bearing the amended labeling:

1. The mis-use statement "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling" must follow the Directions for Use heading as it appeared in the last accepted labeling dated July 11, 1989.
2. Delete the word "Warnings" and replace with the previously accepted heading:

Precautionary Statements
Hazards to Human and Domestic Animals
Caution

3. Remove "benzocaine" from the active ingredient portion of the label and list it beneath the ingredient statement using an asterisk to the total percentage of inert ingredients i.e.,

Inert Ingredients* 90%

* Contains 3% Benzocaine

If you recall in the Agency's letter of December 28, 1994 regarding the reregistration of products containing benzocaine it was determined that benzocaine did not meet the definition of a an active pesticide ingredient as stated in Section 2 of FIFRA. Thus you were required to change benzocaine from an active to inert ingredient. Subsequent to this ~~conclusion~~ you called to inform me that

SYMBOL	since benzocaine is a human drug FDA requires it to be listed on				
SURNAME	<i>Hebert</i>				
DATE	<i>1-24-96</i>				

the label. You suggested and we agreed that in order to satisfy both FDA/EPA regulations you would remove benzocaine from the active ingredient section of the label and list it beneath the ingredient statement as indicated above. Once FDA publishes a final monograph establishing the safe and effective use of this drug the product will be deregulated as a pesticide under FIFRA and regulated solely by FDA as a human drug.

The CSF dated for May 2, 1995 is not acceptable for the following reasons:

- 1. The source product for precipitated sulfur (EPA Reg. No. 476-168) has been canceled since October 7, 1983. You must specify a currently registered source product for precipitated sulfur under Column 12.
- 2. Is this CSF for the basic or alternate formulation? You should indicate this in Block A.
- 3. Please specify the quantity of each component as actually introduced into the formulation under Column 13a.
- 4. The proposed certified limits do not comply with the standard limits specified in 40 CFR 158.175(b)(2).
- 5. The upper and lower certified limits for Propylparaben should be revised so that they are higher and lower, respectively, than the nominal concentration under Column 13b.
- 6. The complete chemical compositions are required for the trade name products listed below. The suppliers should be requested to submit the following information for each component in the trade name product: the chemical name; CAS Registry Number; and the percentage in the product. The suppliers may contact EPA directly referencing this EPA Registration Number in their response.

The trade names are: Adol 52 NF (Carrier Emollient); DC 345 Fluid (Carrier Emollient); Lanette 18 (Carrier Emollient); Texapon K-1296 (Surfactant)

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 yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

PRODUCT NAME: Chigg-Away

3/4

EPA REG. NO: 36864-1

**CHIGG
AWAY**

TWO WAY ACTION

**1-RELIEVES ITCHING DUE TO INSECT BITES,
SUCH AS CHIGGERS (REDBUGS), MOSQUITOES,
TICKS, FLEAS, FIRE ANTS; MINOR STINGS.**

2-REPELS CHIGGERS (REDBUGS)

ACTIVE INGREDIENTS: Propylated Salicyl 15.0%,
Benzocaine U.S.P. 2.0%, MENTHOL 0.5%.

KEEP OUT OF THE REACH OF CHILDREN
CAUTION: SEE BACK PANEL FOR
ADDITIONAL PRECAUTIONS

NET 4 FL. OZ. (118 ML)

6840-01-137-8456

THIS PRODUCT MUST BE FOL-SEALED. IF IMPRINTED INNER
FOIL SEAL IS BROKEN OR MISSING, DO NOT USE

INDICATIONS: 1. RELIEVES ITCHING and discomfort due to non-petersonous insect bites such as chiggers (redbugs), mosquitoes, ticks, sand fleas, no-see-ums, biting flies, fire ants, bees and wasps, swimmers itch. **DIRECTIONS:** Apply topically and rub in well as needed. The unique action of CHIGG-AWAY lotion carries prompt relief to the source of irritation. Provides soothing relief from itching.

2. REPELS CHIGGERS (redbugs). **DIRECTIONS:** Apply around feet, ankles, wrist and to skin under all areas of tight clothing and around all openings in outer clothing. Reapply after heavy perspiration.

WARNING: It is a violation of Federal law to use this product in a manner inconsistent with it's labeling. For external use only. Keep away from eyes or other mucous membranes. Not for protracted use. If the condition for which this product is used persists or if a rash or irritation develops, discontinue use and consult a physician. For use on intact skin only. Do not use on children younger than two years. As with all drugs keep out of the reach of children. In case of accidental ingestion contact a physician or poison control center at once.

DISPOSAL: Do not reuse bottle. Rinse thoroughly before discarding.

NDC NO: 4891-002-4
EPA Reg. No. 36864-1
EPA EST: 68689-NC-001



PIERSON LABORATORIES, INC.
P.O. Box 107 • Saluda, NC 28773

manufactured for

to be added on next printing

ACCEPTED
with COMMENTS
in EPA Letter Dated:

24 JAN 1996

36864-1

HA

CHIGG AWAY

"The Soldier's Choice"

The common belief that chiggers (redbugs) burrow into the skin and suck blood is untrue. A digestive fluid is injected when the mite becomes firmly attached. The itch of the bite is presumably a reaction to the digestive fluid. The myth that you can smother the chigger (redbug) and thereby stop the itch is just that, a myth.

This product is inner foil-sealed. If imprinted inner foil seal is broken or missing, do not use.

CHIGG-AWAY WORKS TWO WAYS

- 1. RELIEVES ITCHING and discomfort due to persistent insect bite such as chiggers (redbugs), mosquitoes, ticks, sand fleas, fleas, lice, etc., biting flies, fire ants, bees and other bothersome life.**
Directions: Apply liberally and rub in well as needed. The unique action of CHIGG-AWAY helps soothe itching relief to the source of irritation. Freshness and relief from itching.
- 2. PREVENTS Chigger bites.**
Directions: Apply around face, neck, waist and to other areas of areas of high activity and around all openings to outer clothing. Reapply after heavy perspiration. For protection of exposed skin to use this product in a constant spray with the clothing. For greatest use only, spray every 30 min, once or twice a day. For protection of exposed skin, if the condition becomes dry, product is used sparingly or if a rash or itching develops, discontinue use and consult a physician. For use on infant skin only. Do not use on children younger than two years. As with all drugs, keep out of the reach of children. In case of poisoning, consult a physician or poison control center at once.
- NEC INC. 4881-0000
 1976 Reg. U.S. Patent & Trademark Office
 MADE IN U.S.A.

EPS will be changed to EPA

Manufactured for

will be added to wording at next printing

ACCEPTED FOR DEPARTMENT OF THE ARMY

24 JAN 1936

36864-1