01/24/1996

UNITED STATES ENVIRONMENTAL PROTECTION ASE

24 JAN 1996

300 5499175 315,443,313 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 the subsequent you called to inform me that symbol since benzocaine is a human drug FIA requires it to be listed on surname

EPA Form 1320-1A (1/90)

DATE

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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:

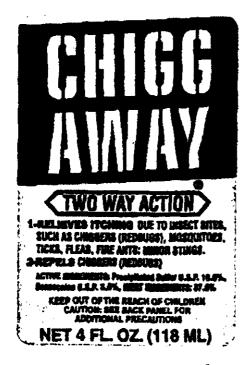
- The source product for precipitated sulfur (EPA Reg. No. 476-168) has been canceled since October 7, 1983. You must specify a currently registered source product for precipitated sulfur under Column 12.
- 2. Is this CSF for the basic or alternate formulation? You should indicate this in Block A.
- 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) EPA REG. NO: 36864-1



6840-01-137-8456

THIS PRODUCT WHICH FOIL-SEALED. IF IMPRIETED HIME!
FOIL SEAL IS BROKEN OF WIREHING, BO HOT USE

BEDICATIONS: 1. ARLEVES ITCHANG and discontent due to respectance where times such as obligates (resturgs), resoultnes, ticks, sand fines, no-new-urns, billing files, for arise, hase and venous automores tich. CHEECTIONS: Apply topically and sub-in well as needed. The unique action of CHEECTIONS total cornes prompt mile! to the source of initiation. Provides accepting relief from fiching. 2. BEPELS CHEECTIONS: (restrongs). DIRECTIONS: Apply around fool, anilso, unjut and to sale under all areas of tight clothing and unused all openings in saler cootling, Raspely after heavy necessicalism.

WARMARY It is a vicinion of teleral law to use this product in a marrier inconsisted, with it's labeling. For external use only, Keep

amy from eyes or either macous manipranes. Not for protocopid use. If the constitut for which this product is used presists or if a rash or irritation develope, lincontinue use and consult a physician, for use on instant side only. Or not use on examples younger than two years, As with all owes, they out of the result of children, in case of accidental ingestion centact a physician or poisson central center at once. IMPOSALE to not reven bettle. Riese thoroughly before discarding.

NOU NOY, 46591-0002-4
EPA Reg. 10 38666-1
EPA EST 68668-86-007



PIERSON LABORATORIES, INC. P.G. Box 107 • Salude, IIC 20773

manufactured for

to be added on next printing

ACCEPTED
with COMMENTS
in EPA Letter Dated.

2 4 JAN 1996

36861-1

EPS will be changed to E.PA



The Soldier's Choice'

The common belief that chippers (redbugs) burrow into the ston and suck blood is untrue. A digestive fluid is injected when the mile becomes firmly attached. The ach of the bite is presumably a reaction to the digestive fluid. The myth that you can sending the chipper (redbug) and thereby stop the fich is just that, a myth.

Manufactured for

ACCEPTED

ONE COMMENTOFFICE BLACE Brace

2 4 JAN 1996

will be added to wording at next printing

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