



Telephone (201) 331-2904

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Passippany, NJ 07054

December 30, 1996

Return Receipt Requested

Mr. Alvin J. Gorin, President
Ambix Laboratories, Inc.
210 Orchard Street
E. Rutherford, New Jersey 07073

REVIEWED BY

AC / 12/97
C.O.

File No.: 97-NWJ-11

Dear Mr. Gorin:

This is in reference to "Blue Gel" which is distributed by your firm. The product is intended for use as a pediculicide and contains, according to the label, 0.3% pyrethrins and 3.0% piperonyl butoxide as the active ingredients.

Pediculicide products for use on humans are regulated as drugs (section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)). "Blue Gel" pediculicide is subject to final regulations covering topical OTC pediculicide products which became effective on December 14, 1994 (Title 21 Code of Federal Regulations part 358.601). Any OTC pediculicide product, including "Blue Gel," that is initially marketed and which does not meet the requirements of the monograph after the effective date is considered a "new drug" (Section 201(p)). A new drug may not be legally marketed in this country unless it is subject to an approved New Drug Application (NDA).

"Blue Gel" is misbranded (section 502 of the Act) because it fails to bear the appropriate "statement of identity" (21 CFR 358.601(a)), it fails to bear all the required directions (21 CFR 358.601(d)(1) & (e)), it fails to bear all of the required warnings (21 CFR 358.601(c)), and it fails to declare the U.S.P. established name of "pyrethrum extract" instead of "pyrethrins."

The above list of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that the drug products you distribute are in compliance with the Act and regulations promulgated under the Act. Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which corrections will be made.

Your reply should be sent to the Compliance Branch, Food and Drug Administration, 10 Waterview Blvd., Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Sincerely,

Edward H. Welton for
Matthew H. Lewis
District Director
New Jersey District

AC:slw