



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Revised by J. News 9/25/98

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
98-DT-17

September 23, 1998

Mr. B. Terrence Reagan, President
Brun Laboratories, Inc.
1120 Monroe St. NW Suite 13
Grand Rapids, MI 49503

Dear Mr. Reagan:

During an inspection of your manufacturing facility located in Grand Rapids, MI conducted on August 26 to September 2, 1998, our investigator determined that you are marketing "Rex Eme® CREAM". The labeling of the various sized containers of "Rex Eme® CREAM" bears claims such as antiseptic, antibacterial, antifungal, keratolytic, and for the treatment of acne, eczema, psoriasis, poison ivy, cold sores, diaper rash, fever blisters, chickenpox, hemorrhoids, dandruff, seborrhea, athletes foot, and ringworm. According to the labeling, the product contains: resorcinol, phenol, camphor, vitamin E, menthol, eucalyptol, petrolatum, steryl and cetyl alcohol, and lanolin.

Based on the claims cited above, "Rex Eme® CREAM" is a drug (Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)). Further the product is subject to the final rules covering OTC acne drugs (Title 21 Code of Federal Regulations (CFR), §333 Subpart D), anorectal drugs (21 CFR §346), antifungal drugs (21 CFR §333 Subpart C), and dandruff, seborrheic, dermatitis, and psoriasis drugs (21 CFR §358 Subpart H).

The formulation and labeling for "Rex Eme® CREAM" does not meet the requirements of any of the final rules cited above. Therefore, the product is a "new drug" (Section 201(p) of the Act), which may not be marketed in interstate commerce (Section 505(a)) unless it is the subject of an approved New Drug Application (NDA) (Section 505(b)). Further, "Rex Eme® CREAM" is misbranded (Sections 502(f)(1) and 502(f)(2) of the Act) because the directions for use and warnings do not comply with the final rules.

We are not aware of any evidence that the combination of ingredients found in "Rex Eme® CREAM" is generally recognized as safe and effective for those indications not covered by the final rules cited above. We also consider "Rex Eme® CREAM" to be a "new drug" (Section 505) and misbranded (Section 502(f)(1)) for those claims in the labeling that are not subject to the final rules noted above. The product is also misbranded (Section 502(e)) because it does not declare the amount of alcohol present.

Also during the inspection, our investigator documented deviations from the current Good Manufacturing Practice Regulations (21 CFR Parts 210 and 211). These deviations cause your drug product to be adulterated within the meaning of Section 501(a)(2)(b) of the Act, as follows:

1. Failure to produce batch production and control records for each batch of drug product produced that includes complete information relating to the production and control of each batch.
2. Failure to document the tests conducted to verify the identity of each component of the drugs manufactured.
3. Failure to establish written specifications for bulk lots of the Rex Eme® Cream received for subsequent packaging, and failure to confirm the identity of the bulk lots.
4. Failure to establish in-process controls and tests or examinations to assure batch uniformity and integrity of the drugs manufactured, and failure to establish written procedures that describe the in-process controls.
5. Failure to have written documentation for the responsibilities and procedures applicable to the quality control unit.
6. Failure to document that each person engaged in the manufacture, processing, packing, or holding of a drug has the education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions.
7. Failure to keep records of equipment cleaning.
8. Failure to document that drug product containers are examined visually for container damage or contamination prior to acceptance.
9. Failure to document that correct labels, labeling, and packaging materials are used for drug products including the examination of packaging and labeling materials before packaging, and documentation of such examination in the batch production record.

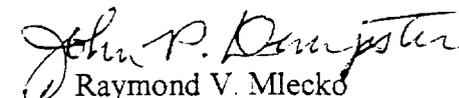
The above listed violations are not intended to be construed as all inclusive of those that exist in your firm. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations, and to ensure that your labeling, including any of your catalogs, and all of your firm's products meet requirements of the Act and its implementing regulations. Federal agencies are advised on the issuance of all Warning Letters about drugs and devices 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 without further notice. This action may include seizure and/or injunction.

Please notify this office within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take to correct the violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207, Attention: David M. Kaszubski, Compliance Officer (Telephone: 313-226-6260 extension 185).

Sincerely,


Raymond V. Mlecko
for Acting District Director
Detroit District