

HF1-35 Reviewed 12/24/96
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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration

Refer to: CFN 112486

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

December 23, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Wayne Van Engelen, President
L'Aprina, Inc.
4716 Lewis Woods Court
Chantilly, Virginia 20151

Re: L'Aprina Liquefied Topical Aspirin,
4 Fl. Oz. Spray, 2 Fl. Oz. Roll-On,
1 Fl. Oz. Squeeze Bottle

Dear Mr. Van Engelen:

During an inspection of L'Aprina conducted on August 8 and 9, 1996 and September 6 and 9, 1996, Food and Drug Administration (FDA) Investigator Patrick Weixel obtained information which indicates that your firm markets the above referenced products.

The label for the three products states that they contain liquefied aspirin as the active ingredient, and that these products are for "the temporary relief of minor aches and pains associated with muscular aches, strains and cramps, arthritis, joint pain, burns, lower back discomfort, bursitis, rheumatism, insect bites and sports injuries." A promotional flyer (labeling) distributed with these products, with the heading "L'Aprina International, Inc....Liquefied Topical Aspirin a Proven Analgesic and Anti-Inflammatory with Aloe Vera," makes additional claims, including "L'APRINA provides relief for a wide range of pain, including burns, insect bites, athlete's foot, migraine headaches, shingles, menstrual cramps, tennis elbow, strained muscles, and other pain which can be relieved with the use of aspirin." Therefore, the three L'Aprina products are drugs, as defined by Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act).

In general, products which are labeled as external analgesic drug products for over-the-counter (OTC) human use are subject to the ongoing review of OTC human drugs.

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However, on November 7, 1990, the FDA issued a Final Rule establishing that over-the-counter (OTC) external analgesic drugs formulated with aspirin as an active ingredient are not generally recognized as safe and effective and, therefore, are misbranded. All such OTC drug products initially marketed after May 7, 1991 are subject to regulatory action if they contain aspirin and are intended as external analgesics (21 CFR Title 21, Code of Federal Regulations, Part 310.545). These products are thus "new drugs" as defined by Section 201(p) of the Act which may not be legally marketed without an approved New Drug Application (Section 505).

Furthermore, these drugs are misbranded in accordance with Section 502(f)(1) of the Act as the labeling fails to bear adequate directions for use for the conditions for which they are offered.

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

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) days, state the reason for the delay, and the time frame within which corrections will be completed. You should notify this office when corrective actions are completed so that a verification inspection can be scheduled. The FDA will then withdraw its advisory to other federal agencies concerning the award of government contracts, and resume review of any pending applications.

Your reply should be sent to Gerald W. Miller, Compliance Officer, U.S. Food and Drug Administration, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046-4200.

Sincerely,

William M. Ment
William M. Ment
Acting Director, Baltimore District