



U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT

850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

492

Telephone: [718] 340-7000 [Ext 5053]

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WARNING LETTER

November 13, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Rawle E. Nicholas, President
Lenco's Products
664 East 237 Street
Bronx, NY 10466

Ref: 6-NYK-98

Dear Mr. Nicholas:

This letter is in reference to your manufacture, marketing, and distribution of the products known as "Wild Root Tonic," "Aunt Betty's Women's Tonic," and "Aunt Linda's Bitters."

Claims for "Aunt Betty's Women's Tonic" include, for example, "used to treat persistent coughs in asthma, bronchitis, and whooping cough," "lowers fevers, helps blood clots," "used to induce menstruation," and "used for birth control and to prevent miscarriages."

Claims for "Aunt Linda's Bitters" include uses such as "a sedative for small children," "helps in virtually all catarrhal problems in the bronchial tubes . . . ," and "helps in problems with gallstones . . . "

Claims for "Wood Root Tonic" include use as a sedative.

Some of the claims for "Aunt Betty's Bitters" and "Aunt Betty's Women's Tonic" cited above cause them to be subject to the final rules on Over-the-Counter (OTC) bronchodilator and expectorant drug products found in part 341 of Title 21 Code of Federal Regulations (21 CFR 341). Neither the formulation nor the labeling for the product conforms to these final regulations, thus causing these products to be "new drugs."

The claims as a "mild herbal sedative" for "Wood Root Tonic" and "a sedative for small children" for "Aunt Linda's Bitters" cause them to be subject to the final rule covering daytime sedative products (21 CFR 310.519) which states that any ingredient offered as a daytime sedative causes the products to be "new drugs."

We consider your promotional literature for these products to be labeling which makes therapeutic claims for these products. These claims cause the products to be drugs [Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)]. These products are also "new drugs" [Section 201(p) of the Act] because there is no evidence that they are generally recognized as safe and effective for their intended uses. Since these products are "new drugs," they may not be marketed in the United States without approved new drug applications [Section 505(a) of the Act].

They are also misbranded as described in Section 502(f)(1) of the Act because the labeling fails to bear adequate directions for use and are false and misleading because the labeling suggests that the products are safe and effective for their intended uses when this has not been established [Section 502(a) of the Act].

Finally, these products are adulterated [Section 501(a)(2)(B) of the Act] because these products are drugs and the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated or administered in conformity with current good manufacturing practice. The minimum current good manufacturing practice regulations for finished dosage forms may be found in 21 CFR 210 and 211.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the FDA without further notice. The Act provides for the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

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Your reply should be sent to Anita Fenty, Compliance Officer; U.S. Food and Drug Administration; New York District; 850 Third Street; Brooklyn, NY 11232.

Sincerely,

A handwritten signature in cursive script, appearing to read "Brenda Holman". The signature is written in black ink and is positioned above the printed name.

Brenda Holman
District Director
New York District Office