



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Chicago District Office
650 W. Jackson/Suite 1600
Chicago, IL 60661
Telephone: (312) 363-6863

November 4, 2002

WARNING LETTER
CHI-28-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. L. Daniel Jorndt, Chairman & CEO
Walgreen Company
200 Wilmot Road
Deerfield, Illinois 60015

Dear Mr. Jorndt:

This is in reference to "Ice Blue Flavored Menthol Cough Suppressant Drops" distributed under the Walgreen Co, Deerfield, IL label. The active ingredient for the product is listed on the label as Menthol 12 mg. In addition to the statement of identity on the principal display panel, this product is identified as being a "cough suppressant" in the "Drug Facts" section of the package label.

Based on the cough suppressant claim, "Ice Blue Flavored Menthol Cough Suppressant Drops" product is a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The product is subject to final regulations covering OTC cough and cold preparations codified at Title 21, Code of Federal Regulations (21 CFR), Part 341. Under these regulations, the dosage for a menthol cough suppressant lozenge is 5 to 10 milligrams. Because the level of menthol in each "Ice Blue Flavored Menthol Cough Suppressant Drops" exceeds this limit, we consider the product to be a "new drug" (Section 201(p) of the Act). Under Section 505(a) of the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution violates Section 505 of the Act.

The above list of violations is not intended to be an all-inclusive list of deficiencies with products distributed by your firm. It is your responsibility to ensure that the drug products you distribute meet all the requirements of the Act and its implementing regulations. 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.

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You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for delay and the time frame within which corrections will be made. Your reply should be addressed to George F. Bailey, Compliance Officer, at the above address.

Sincerely,

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Arlyn H. Baumgarten
Director
Chicago District