



CERTIFIED  
RETURN RECEIPT REQUESTED

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

December 19, 1996

WARNING LETTER  
97-DT-05

Mr. David M. Dickey, President  
DMD Corporation  
15268 Stony Creek Way  
Noblesville, IN 46060

Dear Mr. Dickey:

An inspection was made of your firm on September 3, 1996 by Investigator Jeffrey A. Sommers. The inspection covered the labeling for Ephedrine Plus tablets which is a combination of ephedrine hydrochloride (25 mg.) and guaifenesin (100 mg.). The inspection found serious violations of the Federal Food, Drug and Cosmetic Act (the Act).

Ephedrine Plus, which is a combination OTC bronchodilator and expectorant tablet drug product, is subject to the Final Monograph covering Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-The-Counter Human Use, Title 21, Code of Federal Regulations, Part 341 (21 CFR 341). Any OTC bronchodilator/expectorant drug product initially introduced or delivered for introduction into interstate commerce following the effective date of the monograph, must either conform to the requirements of the monograph or be the subject of an approved new drug application in order to be legally marketed.

Our review of the labeling for Ephedrine Plus found it is labeled to contain 100 mg. of guaifenesin per dose while the monograph requires a strength of 200-400 mg. per dose (21 CFR 341.78(d)). Because Ephedrine Plus is not in compliance with the Final Monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use (21 CFR 341), it is a new drug within the meaning of section 201(p) of the Act, which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Act since no approval of an application filed pursuant to section 505(b) is effective for such drug.

The product is misbranded within the meaning of section 502(f)(1) in that the labeling fails to bear adequate directions for use for the conditions for which it is offered and it is not exempt from this requirement under regulation 21 CFR 201.115 since it is an unapproved new drug within the meaning of section 505(a) of the Act. The product is further misbranded within the meaning of section 502(a) of the Act in that the counter display panel labeling is false or misleading in that it states this product has an "FDA Approved Formula", which is contrary to fact.

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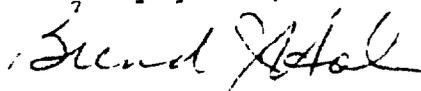
The violations cited in this letter are not necessarily intended to constitute an all-inclusive statement of all of the violations which may exist for products marketed by your firm. You should review all of your firm's products to assure that they are in compliance with the requirements of the Act. Federal agencies are advised of the issuance of all Warning Letters about drugs 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 promptly correct them may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be implemented.

Your response should be directed to Mr. John E. Klemmer, Compliance Officer at the above address.

Sincerely yours,



Brenda J. Holman  
District Director  
Detroit District