DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Rockville, MD 20857

# WARNING LETTER

October 11, 2002

Mr. Bhart Patel
Neil Laboratories Inc
55 Lake Rd
East Windsor, NJ 08520

Products: Guaifenesin SR Caplets 800 mg
Guaifenesin Caplets SR 1200 mg
Guaifenesin SR Caplets 1000 mg

Dear Sir/Madam:

This letter is written in reference to the marketing by your firm of the above products, single ingredient guaifenesin extended release products.

Guaifenesin is a drug that presently has an established general recognition of safety and effectiveness under the OTC Monograph system as an expectorant (21 CFR 341), but the OTC monograph system does not include provisions for extended release dosage form drug products. The agency has, through rule making procedures, accorded new drug status to certain drugs. Included among these are extended release dosage form drugs. Specifically, Title 21 of the Code of Federal Regulations at section 310.502(a)(14), codifies the new drug status of extended release drug products. Therefore, single ingredient guaifenesin extended release drug products are new drugs and require an approved application for marketing.

Before there was a New Drug Application (NDA) approved for a single ingredient guaifenesin extended release product, FDA did not expend scarce enforcement resources to address such unapproved drugs. However, on July 12, 2002, FDA approved NDA 21-282 covering the marketing of Mucinex 600 mg, a guaifenesin extended release tablet expectorant for patients 12 years and above. Other single ingredient extended release guaifenesin drug products, which are new drugs, must be approved under an NDA or abbreviated new drug application (ANDA) as required by the Federal Food, Drug, and Cosmetic Act (the Act).

There are no approved applications under the provisions of Section 505 on file with the FDA for the previously listed products marketed by your firm. Therefore, the marketing of these products without an approved new drug application constitutes a violation of Section 505(a) of the Act.

We request that you reply within fifteen (15) days of your receipt of this letter stating what action you plan to take to bring these products into compliance with applicable requirements. If you no longer market any guaifenesin single ingredient extended release products or believe you have received this letter in error, please notify us of this fact. If appropriate corrective action is not undertaken, the FDA may initiate legal action without further notice. The Act provides for seizure of illegal products or injunction against the manufacturers and/or distributors of illegal products.

The previously identified violation is not intended to be an all inclusive list of violations at your facility. It is your responsibility to assure that your firm is in compliance with all established requirements.

Your response to this letter should be directed to the attention of Ms. Sakineh Walther, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

/s/

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration