



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
 PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION
 ROCKVILLE, MARYLAND 20857

JAN 7 1981
 10 00 AM - 7 PM '81
 Primary Enforcement Staff

Jim Allen
 Senior Chemist
 National Pharmaceutical Mfg. Co.
 7205 Windsor Blvd.
 Baltimore, MD 21207

Dear Mr. Allen:

Reference is made to your letter of November 25, 1980 and our telephone conversation of December 10, 1980.

As promised, I am forwarding a copy of the FEDERAL REGISTER publication (of December 19, 1980) extending the effective date for required relabeling of OTC oral nasal decongestant drug products containing pseudoephedrine.

As I explained in our telephone conversation, the FDA has not taken a position on combination products containing pseudoephedrine. In the interim, your company can continue to follow the Cough-Cold Panel's dosage recommendations as contained in the Panel's report. Most combinations are covered by the Panel's dosage recommendations of an every 4 to 6 hour dosage for almost all cough-cold ingredients. In a few instances, reformulation and additional stability testing might be necessary where it is necessary to increase the amount of drug in a product to obtain an every 6 hour dose, e.g., dextromethorphan.

I hope this information is helpful.

Sincerely yours,

Gerald M. Rachanow

Gerald M. Rachanow
 Deputy Director
 Division of OTC Drug Evaluation
 Bureau of Drugs

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