

HFA-305
DOCKET #
76N0052

ADMIN PROCEEDINGS STAFF

JAN 26 1981

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Milton A. Bass, General Counsel
George Schwartz, Executive Director
National Association of Pharmaceutical Manufacturers
747 Third Avenue
New York, New York 10017

Dear Messrs. Bass and Schwartz:

I am writing in response to your December 22, 1980 letter addressed to Commissioner Goyan in which you requested that the final order concerning a revised dosage limit for over-the-counter (OTC) drug products containing pseudoephedrine published in the Federal Register of September 30, 1980 be stayed until the appropriate dosage and label copy is published in the final monograph. You specifically stated that without agency guidelines for combination products containing pseudoephedrine you do not have the necessary information to rewrite the dosage and administration section of the labeling for these products.

In the Federal Register of December 19, 1980 (45 FR 83671, copy enclosed), the Food and Drug Administration extended until May 1, 1981 the date by which manufacturers of OTC oral nasal decongestant drug products containing pseudoephedrine are required to comply with the agency's revised dosage limit. The effective date was extended in response to petitions from two manufacturers who believed that the agency's initial effective date of January 30, 1981 did not allow enough time to reformulate and relabel fixed combination products to conform to the new reduced pseudoephedrine dosage limitation.

The proposed monograph of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products included recommended labeling for combination products. A final determination of the appropriate labeling and dosage limitations for OTC combination products containing pseudoephedrine will be made by the agency in the final monograph for these OTC drug products. Until a final monograph is published manufacturers may follow the Cough-Cold Panel's dosage recommendations as contained in the proposed monograph. 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

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necessary where the amount of an ingredient is increased in a product to obtain an every 6 hour dose, e.g., dextromethorphan. The agency advises that specific questions concerning the labeling for products containing pseudoephedrine be directed to the Division of Over-the-Counter Drug Evaluation (HFD-510) Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

We hope this information will be helpful. However, should you wish to pursue the matter you may formally petition the agency for further action.

Sincerely yours,

Marilyn L. Watson
Consumer Safety Officer
Bureau of Drugs

Enclosure

cc:

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Prepared by HFD-30:MWatson:mah:1/26/81

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