

NATIONAL

PHARMACEUTICAL MFG. CO.

A DIVISION OF BARRE-NATIONAL INC.

7205 Windsor Blvd. / Baltimore, Md. 21207 / phone (301) 298-1000

Certified Mail #2452531

November 25, 1980

Bureau of Drugs (HFD-510)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

ATTN: Mr. William E. Gilbertson

Dear Mr. Gilbertson,

Reference is made to the Federal Register Vol. 45, No. 191 dated Tuesday, September 30, 1980, concerning the Decision on Dosage of Pseudoephedrine Preparations (Docket No. 76N-0052).

We feel the 4 month deadline given Pharmaceutical Manufacturers to relabel their OTC oral nasal decongestant drug products containing pseudoephedrine is much too restrictive for the following reasons:

- (1) We are in the fall and winter seasons where the demand for these products are greatest.
- (2) The FDA has no labeling guidelines to be used for combination products containing Pseudoephedrine (letter attached). There is some confusion as to how to relabel these products. It should be noted that since the adult oral dosage of pseudoephedrine has been reduced to 60 mg. every 6 hours the other ingredients, such as antihistamines, cough suppressant, antipyretics and expectorants which may be used in combination, will be affected by the dosage change of pseudoephedrine. These ingredients usually require a 4 hour dosage regimen.
- (3) The OTC Review Panel recommended a 60 mg. dose every 4 hours for this ingredient in their September 9, 1976 proposed monograph on OTC products. The FDA did not take exception to this finding at that time and to our knowledge has not published any proposal for changing it since that time.

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- (4) The Dow Chemical Co. submitted data to support the company's request that the category I adult oral dosage of pseudoephedrine be reduced, on December 1, 1976. Since it has taken the Food and Drug Administration over 3-1/2 years to review the data, the rush to implement this change in the 4 month time frame given manufacturers, is not understandable.

Therefore, we are requesting the Food and Drug Administration to lengthen the time period for manufacturers to change their labeling, to 12 months for products containing pseudoephedrine as a single ingredient. We request the FDA to wait until a final determination of the appropriate dosage limitations for OTC pseudoephedrine combination preparations is made in the final monograph, before requiring any change.

Sincerely,

NATIONAL PHARMACEUTICAL MFG. CO.

Jim Allen

Jim Allen
Senior Chemist

JA/ck
Enc.



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

OCT 31 1980

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

Dear Mr. Allen:

This responds to your letter of October 16, 1980 concerning the Decision on Dosage of Pseudoephedrine Preparations (Docket No. 76N-0052).

The FDA has not issued any labeling guidelines to be used for combination products containing pseudoephedrine. Such guidelines will be worked out as the agency develops its position on combination cough, cold, allergy, bronchodilator, and antiasthmatic drug products. Thus at this time, we currently have no literature which you can use as a reference in rewriting the Dosage and Administration sections of the labeling for your products containing pseudoephedrine.

We are sorry we are unable to be helpful at this time.

Sincerely yours,

William E. Gilbertson, Pharm. D.
Director
Division of OTC Drug Evaluation
Bureau of Drugs

MEMORANDUM

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

TO : Dockets Management Branch (HFA-305)

DATE: JAN 7 1981

FROM : Director
Division of OTC Drug Evaluation (HFD-510)

SUBJECT: Material for Docket No. 76N-052N

- The attached correspondence should be placed on public display under the above referenced Docket No.
- This correspondence should be cross-referenced to Comment _____.

1981 JAN 7 PM 3:30
Administrative Staff



William E. Gilbertson, Pharm. D.

Attachment