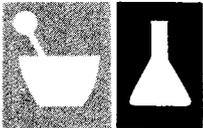


**NAPM**



ADMIN PROCEEDINGS

1981 JAN 14 AM 10:31

**National Association of Pharmaceutical Manufacturers**

747 Third Avenue, New York, New York 10017 •

EXECUTIVE SECRETARIAT Food and Drug Administration			
Routing	Action	Info	Coord
<del>GC-1</del>	✓		
HFA-305		✓	
HED-1		✓	
HF-1		✓	
HF-2		✓	
Director for		<input type="checkbox"/> Direct	
Secretary of		Date	
<i>imp HED-1</i> <i>Direct HFY-1</i> <i>HFJ-20</i>			

GEORGE DOWDEN  
President

MILTON A. BASS  
General Counsel

GEORGE SCHWARTZ  
Executive Director

December 22, 1980

Jere E. Goyan, Ph. D.  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Md. 20852

Re: (Docket No. 76N-0052) Federal Register, Volume 45, No. 191 Tuesday, Sept. 30, 1980 (Pages 64709, et seq.) Cold, Cough, Allergy Bronchodilator, and Anti-Asthmatic Drug Products for OTC Human Use; Decision on Dosage of Pseudoephedrine Preparations

Request for Extension of Time to Comply with This Notice

Dear Commissioner Goyan:

The National Association of Pharmaceutical Manufacturers represents a large segment of the smaller drug manufacturers throughout the country.

Many of our members will be adversely affected by the short time frame (4 months) to revise both formulations and labels. This Notice was published in September. Most manufacturers and distributors order their printing for a minimum of six months to one year. Product manufacture in many cases is projected in the same time frame.

The FDA has not as yet issued any guidelines to be used for combination products containing pseudoephedrine. The agency has stated that: "Such guidelines will be worked out as the agency develops its position on cough, cold, allergy, bronchodilator, and anti-asthmatic drug products." Thus at this time, we do not have the necessary information to rewrite the dosage and administration sections of the labeling for products containing Pseudoephedrine.

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76N-052N

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Jere E. Goyan, Ph. D.  
Commissioner, F.D.A.

December 22, 1980

We respectfully request that this final order be stayed until the appropriate dosage and label copy is published in the final monograph.

Implementation at this time will result in unnecessary waste of dollars and material. The manufacturer must, of course, pass this cost on to the consuming public and various government agencies who are certainly pressed for funds in our current inflationary spiral.

Thank you for giving this matter your kind consideration.

Sincerely,



MILTON A. BASS  
General Counsel



GEORGE SCHWARTZ  
Executive Director

EXECUTIVE SECRETARIAT  
Food and Drug Administration

Routing	Action	Info	Coord
HFD-1	✓		
GDPE-1			✓
HFC-1			✓
HEA-305 (Original)	✓		
HF-1			✓
HF-2			✓
Prepare for	<input type="checkbox"/> Direct		
Signature of:	Reply		
Remarks:	and HFY-1 Direct * HFJ-20		

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