

ADMIN PROCEEDINGS STAFF  
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Ref: 85-108

May 15, 1985

Dockets Management Branch [HFA-305]  
Food and Drug Administration  
Room 4-62  
5600 Fishers Lane  
Rockville, Maryland 20857

Re: [Docket No. 76N-052N; Cold, Cough, Allergy, Bronchodilator,  
and Antiasthmatic Drug Products for Over-the-Counter Human  
Use: Tentative Final Monograph for OTC Nasal Decongestant  
Drug Products]

Dear Madam:

The January 15, 1985 Federal Register contained the above notice of proposed rulemaking. Interested persons were invited to submit written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs by May 15, 1985.

These comments are filed by Plough, Inc., a manufacturer of many drug products, including cough/cold products.

In addition to the comments set forth below, we endorse the comments of the Proprietary Association, of which we are a member and those of Schering Corporation, an affiliated company located in Kenilworth, New Jersey.

#### RECOMMENDED ADDITION TO PEDIATRIC DOSAGE SCHEDULES

Plough has, for many years, marketed a product, St. Joseph Cold Tablets for Children, which is a combination of an internal analgesic/nasal decongestant product.

As noted in comments filed on December 3, 1976, by Schering-Plough to Docket 76N-052N [OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Products], there is an incompatibility between the pediatric dosage schedule for aspirin/acetaminophen and nasal decongestant ingredients.

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We are requesting that an additional optional dosage be included in the dosage schedule for nasal decongestants which would allow a compatible dosage schedule for such a combination product.

Detailed rationale for the optional dosage schedule was discussed at a meeting at FDA on February 25, 1985 [Minutes of meeting filed in Docket 76N-052H, MM002]. In essence, this schedule sub-divides the pediatric age groups as follows:

Age	2 to under	4 years
Age	4 to under	6 years
Age	6 to under	9 years
Age	9 to under	11 years
Age	11 to under	12 years

This age breakdown matches the age breaks in the Internal Analgesic, Antipyretic and Antirheumatic Products Proposed Monograph [proposed 21CFR 343.10(a)(2) and (b)(2) and 343.12(a)(2) and (b)(2)].

We are proposing that this age grouping would be consistent with the needs of the growing pediatric patients and provide an appropriate level of each ingredient.

Based on a careful review of fractions of the adult dosage, it was determined that the most appropriate fraction was one-eighth of the adult dosage.

Based on this method, the following dosages are proposed:

<u>Age</u>	<u>Pseudoephedrine</u> <sup>1</sup>	<u>Phenylpropanolamine</u> <sup>2</sup>
2-3	15.0 mg	6.25 mg
4-5	22.5	9.375
6-8	30.0	12.5
9-10	37.5	15.625
11	45.0	18.75

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<sup>1</sup> Based on a pediatric dosage unit of 7.5 mg.

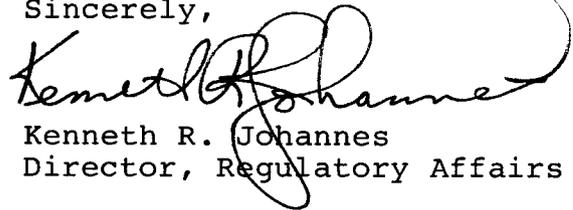
<sup>2</sup> Based on a pediatric dosage unit of 3.125 mg.  
(It is acknowledged that phenylpropanolamine was specifically excluded from this notice, but the dosages are included for comparison purposes.)

It is requested that this optional dosage schedule be added to the current dosage schedules to accommodate products intended primarily for pediatric populations.

The current schedule should also be retained for products intended primarily for adult populations.

We thank you for the opportunity to submit these comments.

Sincerely,



Kenneth R. Johannes  
Director, Regulatory Affairs

KRJ/oso

Submitted in quintuplicate.