

MILES
ADMIN PROCEEDINGS STAFF
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Frederick G. Giel
Assistant Counsel

May 10, 1985

Miles Laboratories, Inc.
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Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 4-62
5600 Fishers Lane
Rockville, MD 20857

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

Dear Sir/Madam:

The captioned notice of proposed rulemaking appeared in the January 15, 1985 Federal Register. Interested persons were invited to submit written comments, objections, or requests for oral hearing by May 15, 1985. Pursuant to that notice, these comments are filed on behalf of Miles Laboratories, Inc.

Miles is a diversified health care company with corporate headquarters in Elkhart, Indiana. Miles manufactures and sells a wide range of products including consumer goods, prescription and nonprescription medicinal products, diagnostics, hospital products and food ingredients. Miles' interest in the notice of proposed rulemaking is a result of its commitment to responsible self-medication.

Miles believes that the status of phenylephrine bitartrate should be clarified in the Final Monograph and that a Category I designation should be assigned at that time. Miles filed data on phenylephrine bitartrate in its submission dated October 10, 1972. Miles indicated that phenylephrine bitartrate, while not as commonly used as the hydrochloride salt of phenylephrine, had the same characteristics. The proposed dose of phenylephrine hydrochloride in adults is 10 mg; that amount is equivalent to approximately 15.5 mg of phenylephrine bitartrate. The Advisory Panel did not address the bitartrate form in its report of September 6, 1976, nor was it addressed in the January 15 Tentative Final Monograph. Miles believes that phenylephrine bitartrate should be classified as a Category I nasal decongestant. The non-inclusion appears to be an inadvertent omission.

76N-052N

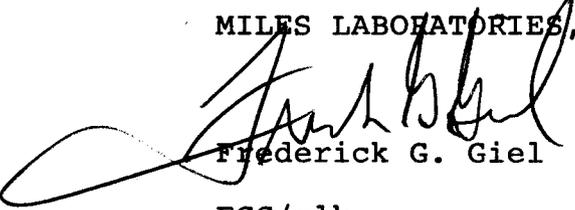
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In addition to the specific comment stated above, Miles wishes to express its support and agreement with the comments filed by The Proprietary Association. In particular, Miles regrets the absence of phenylpropanolamine preparations from the proposal; those preparations have been safely used for decades and Miles urged the expeditious resolution of outstanding questions regarding phenylpropanolamine.

Should you have any questions, please feel free to contact me.

Very truly yours,

MILES LABORATORIES, INC.



Frederick G. Giel

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