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**Boehringer
Ingelheim**

May 9, 1985

Boehringer Ingelheim
Pharmaceuticals, Inc.
a subsidiary of
Boehringer Ingelheim Corporation
90 East Ridge
P.O. Box 368
Ridgefield, Connecticut 06877

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

RE: Docket No. 76N-052N: Tentative Final Monograph for Over-The-Counter
Nasal Decongestant Drug Products

Dear Sirs:

Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) submits the following comments and recommendations for the OTC Nasal Decongestant Tentative Final Monograph published in the Federal Register (50 F.R. 2220, January 15, 1985). BIPI currently markets Nostrilla™ and Nostril® pump sprays containing oxymetazoline and phenylephrine, respectively.

BIPI supports FDA's recent proposal (50 F.R. 15810, April 22, 1985) to allow the necessary flexibility in OTC product labeling. Consumer labeling must be accurate, but it also must be understandable and meaningful. For example, options should be available in proposed CFR 341.80:

Special target audience positioning should be permitted, such as for colds, for allergy, for sinusitis, i.e., all the possible proposed indications for nasal decongestants should not be required. Specific products may be designed for specific indications.

The language for warnings for topical nasal sprays and drops does not apply to the innovative and unique one-way metered pump delivery system of Nostrilla™ and Nostril®. Generally speaking, warnings concerning heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urinating, should not be required for topical nasal decongestants, since systemic distribution of the decongestant is minimal. In the case of our metered delivery system, BIPI particularly believes that such warnings should be eliminated (341.80 (2) (iii)(b)). The metering system of Nostrilla™ and Nostril® substantially reduces dosage variability, assuring that uniform dosage and spray pattern are provided, thereby further minimizing any possibility of significant systemic absorption and systemic side effects.

BIPI also disagrees with two other warnings peculiar to topical dosage forms other than our metered pump. We believe that the spray pattern

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achieved with our pump virtually eliminates the nasal irritation and rebound congestion sometimes associated with conventional sprays and drops. Our marketing experience has confirmed the purpose of the pump's design such that we believe that warnings concerning burning, stinging, etc., and a restriction to only three days' dosage should not be required for our metered pump (341.80 (i)(2)(a) and 341.80 (iii)(a)).

BIPI believes that other accurate statements are appropriate for topical decongestants, e.g., "long lasting relief" for oxymetazoline-containing decongestant products. In addition, due to design provisions of our one-way metered pump, BIPI recommends that accurate statements such as "won't draw back nasal fluids", "unique one-way pump prevents draw-back contamination", "protects against draw-back contamination", and "unique metered spray delivers a controlled/metered dose" be allowed.

Sincerely,



C. Richard Tamorria, Ph.D.
Associate Director
Drug Regulatory Affairs

CRT:cac