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ADMIN PROCEEDINGS STAFF
1985 MAY 15 AM 9:36

May 14, 1985

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

Re: Docket No. 76 N-052N
Tentative Final Monograph for OTC
Nasal Decongestant Drug Products

Dear Sir or Madam:

Burroughs Wellcome Co. is a manufacturer of human pharmaceutical products including over-the-counter nasal decongestants. We join in the comments the Proprietary Association has submitted to the docket for the above-referenced Tentative Final Monograph published at 50 Fed. Reg. 2200-2241 (January 15, 1985) and also offer the following additional comment.

> Proposed warning 21 CFR § 341.80(c)(ii)(a): "Do not exceed recommended dosage because at higher doses nervousness, dizziness, or sleeplessness may occur."

We recommend that the warning be rewritten to read: "Do not exceed recommended dosage. If nervousness, dizziness, or sleeplessness occur, consult a doctor."

"Do not exceed recommended dosage" is an important prohibition for the consumer. It indirectly points out that the nasal decongestant in question is present in full strength and that adverse effects might occur if the dosage recommendation is exceeded.

"If nervousness, dizziness, or sleeplessness occur, consult a doctor" advises the consumer of appropriate circumstances in which a physician's advice is needed before continuing the product's use. A physician would combine patient medical history information along with drug and professional knowledge in advising whether to continue the same dose, decrease the dose or discontinue the drug.

Sincerely yours,

BURROUGHS WELLCOME CO.

Ann E. Salitsky

Ann E. Salitsky
Assistant Counsel

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