

NDA 20-640

S-002

Approval Letter

NDA 20-640/S-002

OCT 17 1997

Novartis Consumer Health, Inc.
560 Morris Avenue
East Hanover, New Jersey 07901-1312

Attention: Cynthia Psaras, Ph.D.
Manager, Regulatory Affairs

Dear Dr. Psaras:

Reference is made to your supplemental new drug application dated May 22, 1997 submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tavist-D (clemastine fumarate 1.34mg/phenylpropanolamine hydrochloride 75 mg extended release) Caplets.

We acknowledge receipt of your submissions dated July 2, and September 11, 1997.

This supplemental application provides for the use of clemastine for treatment of common cold symptoms.

We have completed the review of this supplemental application as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the mock-up draft labeling submitted on May 22, 1997. The gold seal with "ORIGINAL PRESCRIPTION STRENGTH" should be removed at the next printing or 6 months, whichever occurs first.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplemental NDA 20-640/S-002." Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

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Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Ms. Parinda Jani, Project Manager, at (301) 827-1064.

Sincerely yours,

John K. Jenkins, M.D., F.C.C.P.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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CC:

ORIGINAL NDA 20-640

HFD-570/DIV. FILES

HFD-570/CSO/P.JANI

HFD-570/SCHUMAKER/10-15-97

HFD-570/JOHNSON/10-15-97

HFD-570/MEYER/10-16-97

HFD-570/SANCILIO/

HFD-570/SUN/

HFD-570/CONNER

HFD-570/KIM/

HFD-570/POOCHIKIAN/10-16-97

HFD-2/M.LUMPKIN/

HFD-560/OTC (WITH LABELING)

HFD-102/ (WITH LABELING)

DISTRICT OFFICE

HF-2/MEDWATCH (WITH LABELING)

HFD-92 (WITH LABELING)

HFD-40/S.SHERMAN (WITH LABELING)

HFD-613 (WITH LABELING)

HFD-735

HFD-820/Y.Y.CHIU

HFD-560 (WITH LABELING)

R/D BY: PJani/10-06-97

F/T BY: LSlaybaugh/10-17-97

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FINAL:

APPROVAL

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