DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-082

Novartis Consumer Health
560 Morris Avenue
Summit, NJ 07901-1312

Attention: Nico Nicolaou
Manager
Regulatory Affairs

Dear Mr. Nicolaou:

Please refer to your new drug application (NDA) dated October 7, 1999, received October 8, 1999, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Tavist Allergy/Sinus/Headache (0.335 mg clemastine fumarate/30 mg pseudoephedrine sulfate/500 mg acetaminophen) Tablets.

We acknowledge receipt of your submissions dated October 20, 1999, and March 1, 10, and 31, May 3, 8, and 18, June 14 and 15, September 7, October 30 and November 9, 2000, and January 2 and 15, February 1, 14, 22, and 23, 2001. Your submission of September 7, 2000, constituted a complete response to our August 4, 2000, action letter.

This new drug application provides for the use of Tavist Allergy/Sinus/Headache (clemastine fumarate/pseudoephedrine sulfate/acetaminophen) Tablets for temporary relief of symptoms associated with hay fever, allergic rhinitis, and the common cold.

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

The final printed labeling (FPL) must be identical to the labeling for the blister submitted on September 7, 2000, and the immediate carton submitted on November 9, 2000 (24- count and 48-count carton presentations). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 NDA 21-082." Approval of this submission by FDA is not required before the labeling is used.

As agreed in your amendment of February 23, 2001, bold the statement, "Avoid excessive heat," found

in the carton labeling under *OTHER INFORMATION*, prior to the next printing or within 6 months, whichever comes first.

We remind you of your postmarketing study commitment in your submission dated February 1, 2001. This commitment is described below.

> Development, validation, and submission in a prior approval supplement, of a new method for estimation of chromatographic impurities in the drug substance, clemastine fumarate.
>
> Final Report Submission: On or before June 30, 2001

Submit chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to this postmarketing study commitment must be prominently labeled "Postmarketing Study Final Report" or "Postmarketing Study Correspondence."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

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

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products. If you have any questions, contact Ms. Babette Merritt, Project Manager, at (301) 827-2222.

Sincerely yours,

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Charles Ganley, M.D.
Director
Division of Over-The-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

/S

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research