CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-025

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 21-025

APR 21 2000

Novartis Pharmaceuticals Corporation
Attention: Robert W. Kowalski, Pharm.D.
59 Route 10
East Hanover, NJ 07936-1080

Dear Dr. Kowalski:

Please refer to your new drug application (NDA) dated Augustl 11, 1998, received August 12, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Exelon (rivastigmine tartrate) solution 2.0 mg/mL.

We also acknowledge receipt of your submissions dated:

October 22, 1999 March 17, 2000 April 21, 2000

Your submission of October 22, 1999 constituted a complete response to our September 8, 1999 action letter.

This new drug application provides for the following Indication.

> "Exelon is indicated for the treatment of mild to moderate dementia of the Ahzheimer's type."

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). 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 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 NDA 21-025." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment specified in your submission to your companion application for Exelon Capsules (NDA 20-823) dated April 20, 2000.

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.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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, call Robbin Nighswander, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely,

/S/

Russell Katz, M.D.
Director
Division of Neuropharmacological
Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure (Draft Package Insert)