CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-823

ENVIRONMENTAL ASSESSMENT and/or FONSI

ORIGINAL

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NOVARTIS

September 23, 1997

Paul Leber, MD
Director
Division of Neuropharmacological
Drug Products/HFD-120
Office of Drug Evaluation I
Attn: Document Control Room
Center for Drug Evaluation and Research
Woodmont II, 1451 Rockville Pike
Rockville, Maryland 20852

NDA No. 20-823

EXELON™ (rivastigmine tartrate) Capsules

AMENDMENT TO NDA: WITHDRAWAL OF EA AND APPLICATION FOR WAIVER

ORIG AMENDMENT
N (30)

Dear Dr. Leber,

Please refer to our pending New Drug Application for Exelon™ (rivastigmine tartrate) Capsules.

In accordance with the Revised Policies and Procedures for compliance with the National Environmental Policy Act as published in the Federal Register on July 29, 1997 we hereby request withdrawal of the Environmental Assessment provided in Volume 14, pp. 3-2957 to 3-3138 of the original Exelon™ NDA, No. 20-823, submitted on April 7, 1997.

As requested in the above referenced Federal Register notice, the present submission also provides a claim for categorical exclusion from the Environmental Assessment requirements under 21 CFR 25.31(b). This provides for action on an NDA whereby the use of the active moiety may be increased, but the estimated concentration of the active moiety rivastigmine at the point of entry into the aquatic environment will be below 1 part per billion. Documentation to support the claim for categorical exclusion can be found in the attachment immediately following this letter.

If you have any comments or questions with regard to this submission, please contact the undersigned at (973) 503-6869.

Sincerely,

Robert W. Kowalski, Pharm.D.
Associate Director,
Drug Regulatory Affairs

Attachment
Submitted in Duplicate

cc: Ms. Regina Brown, New Jersey District Office

E. ENVIRONMENTAL ASSESSMENT

A claim for categorical exclusion from the Environmental Assessment requirements under 21 CFR 25.31(b) - Action on an NDA, abbreviated application, or a supplement to such applications, or action on an OTC monograph - if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 ppb.

As set forth in 21 CFR Part 25.31(b), action on a New Drug Application is categorically excluded from the requirement to prepare an Environmental Assessment or an Environmental Impact Statement if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be less than 1 part per billion (ppb). "Increased use", as defined in 21 CFR Part 25.5(a), will occur if the drug is "administered at higher dosage levels, for longer duration or for different indications than were previously in effect, or if the drug is a new molecular entity."

Novartis Pharmaceuticals Corporation has filed a New Drug Application for Exelon™ (rivastigmine tartrate) capsules. Novartis Pharmaceuticals Corporation certifies that this submission for the new molecular entity, rivastigmine tartrate, qualifies for a categorical exclusion in accordance with 21 CFR Part 25.31(b) as the concentration of the new active moiety rivastigmine base will be significantly less than 1 ppb. Please refer to confidential Attachments 1 and 2 which are provided in support of this claim.

Further, Novartis Pharmaceuticals Corporation states that, to the best of its knowledge, no extraordinary circumstances exist which may significantly affect the quality of the human environment and would thus require the preparation of at least an Environmental Assessment.

APPEARS THIS WAY
ON ORIGINAL