

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-025

PHARMACOLOGY REVIEW(S)

Barry N. Rosloff, Ph. D.
8/24/99

PHARMACOLOGIST REVIEW OF NDA 21-025
ORIGINAL SUMMARY

SPONSOR: Novartis Pharmaceuticals Corp.
59 Route 10
East Hanover, N.J. 07936

DRUG: rivastigmine (Exelon) oral solution

CATEGORY: cholinesterase inhibitor for treatment of Alzheimer's Disease

RELATED NDA: NDA 20-823 (Same sponsor, for Exelon capsules)

SUMMARY AND EVALUATION:

Cross reference is made to NDA 20-823. The preclinical data in the latter were reviewed by me (Original Summary of 10/26/97) and the application was considered approvable from the preclinical standpoint. No new animal data are necessary for the present application. There are no unusual excipients in the new formulation.

RECOMMENDATIONS:

This NDA is approvable.

Comments concerning the labeling made in my 10/26/97 review of NDA 20-823 are also applicable to the present NDA.

BSH
Barry N. Rosloff, Ph.D.

SUPERVISORY CONCURRENCE:

BSI
Glenna Fitzgerald, Ph.D.

cc: NDA 21-025, original+division file
Rosloff, Fitzgerald, Nighswander