

Peter M. Ripley, M.D.  
Clinical Studies  
23H White's Path  
South Yarmouth, Massachusetts 02664

FEB 24 1998

Food and Drug Administration  
Rockville MD 20857

Dear Dr. Ripley:

In October and November 1997, Ms. Sandra P. White, representing the Food and Drug Administration (FDA), conducted an inspection of your conduct, as Principal Investigator, of a clinical study of the investigational drug Exelon (SDZ ENA 713), performed for Sandoz Pharmaceuticals Corporation (now Novartis). This inspection is a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to validate clinical studies on which drug approval may be based and to assure that the rights and welfare of the human subjects of those studies have been protected.

From an evaluation of the inspection report, of the documents collected during the inspection, and of your November 10, 1997 letter to Ms. Carolanne Currier of our office, we conclude that you did not adhere to pertinent federal regulations and/or good clinical investigational practices governing your conduct of clinical investigations and the protection of human subjects in the following respects: An investigator is required to prepare and maintain adequate and accurate case histories. 21 CFR 312.62(b). Your case histories should capture observations made during the trial including identification of each subject and each subject's related study documents.

Please make appropriate corrections/changes in your procedures to assure that the findings noted above are not repeated in any ongoing or future studies.

We appreciate the cooperation shown Ms. White during the inspection.

Sincerely yours,

*st*  
Bette L. Barton, Ph.D., M.D.  
Chief  
Clinical Investigations Branch  
Division of Scientific  
Investigations  
Office of Compliance  
Center for Drug Evaluation  
and Research

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CFN:

Field classification: VAI

Headquarters classification:

- 1) NAI
- 2) VAI-no response required
- 3) VAI-response requested

If Headquarters classification is different classification, explain why:

Deficiencies noted:

- inadequate consent form
- inadequate drug accountability
- failure to adhere to protocol
- inadequate records
- failure to report ADRS \_\_\_\_\_
- other (specify) \_\_\_\_\_

CC:

HFA-224

HFD-344

HFD-340

HFR-NE250 \_\_\_\_\_

HFR-NE250 \_\_\_\_\_

HFD-120 Review Division Div. Dir./Doc. Rm.: NDA#20-823

MO: M. Sevka CSO: L. Chen

r/d: RSKYoung: 2/20/98  
corrected: slk: 2/20/98

**APPEARS THIS WAY  
ON ORIGINAL**