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Food and Drug Administration
Rockville MD 20857

AFR - 6 1998

Patricia A. Walicke, M.D., Ph.D.
Athena Neurosciences
800 Gateway Boulevard
South San Francisco, California 94080

Dear Dr. Walicke:

On September 2-17, 1997, Ms. Stephanie E. Hubbard, 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, a September 23, 1997 letter from Mr. Michael Jann to Ms. Hubbard, and your March 26, 1998 conversation with Dr. Robert Young 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 ensure that the requirements relating to obtaining informed consent and institutional review board review and approval are met. 21 CFR 312.53(c)(1)(vi)(d). You should submit recruitment advertisements to your IRB for their review and approval. You should obtain timely IRB approval of protocol amendments and revise your written informed consent document as appropriate. You should report serious adverse reactions to your IRB in a timely manner.

We note that your study was conducted at two separate sites and was reviewed by two different IRBs. There appeared to be some difficulty in the administration of the study.

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

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

Sincerely yours,

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

cc:
Michael Jann, PharmD.
Mercer University
3001 Mercer University Drive
Atlanta, GA 30341

**APPEARS THIS WAY
ON ORIGINAL**

CC:

HFA-224
HFD-120 Review Division Div. Dir./Doc. Rm.: NDA#20-823
HFD-120 MO:
HFD-120 PM:
HFD-340/R/F
HFD-344
HFR-SE150 DIB
HFR-SE150 BIMO Monitor
HFR-SE150 Field Investigator Hubbard

CFN:

Field classification: not classified
Headquarters classification:

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

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
- Failure to obtain timely IRB review of amendments,
and consents

r/d:RSKY:3/26/98
corrected:slk:3/31/98

APPEARS THIS WAY
ON ORIGINAL