



MAR 17 1998

Dr. Peter Dal-Bianco
Universitätskliniken für
Neurologie
Währinger Gürtel 18-20
A-1090 Wien
AUSTRIA

Dear Dr. Dal-Bianco:

Between December 1-5, 1997, Ms. M. Patricia Murphy and Dr. Robert Young, 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 Novartis Pharmaceuticals Corporation (formerly Sandoz Pharma Ltd.). 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.

Although your clinical study was conducted under an Investigational New Drug Exemption (IND) held by Novartis and you signed a Form FDA 1572 Statement of Investigator, it was clear in discussions with you during the inspection that you were unaware at the time you signed the Form to what exactly you were committing yourself. From an evaluation of the inspection report and of the documents collected during the inspection, we conclude that there were some departures from pertinent federal (FDA) regulations and/or good clinical investigational practices governing your conduct of clinical investigations and the protection of human subjects. We share these with you for your information should you conduct another study under an IND. As was discussed with you by Ms. Murphy and Dr. Young, FDA has specific rules for example as to the membership of ethic committees, the implementation of protocol amendments, the inventory of study medications, identification of all documents related to a study, and documentation of the initial condition and medical progress of subjects during the course of a study.

We appreciate the cooperation shown Ms. Murphy and Dr. Young during the inspection.

Sincerely yours,

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

**APPEARS THIS WAY
ON ORIGINAL**

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CFN:

Field classification: AE

Headquarters classification:

- 1) NAI - in compliance with local rules
- 2) VAI - no response required
- 3) VAI - response requested

If Headquarters classification is different classification, explain why:

CC:

HFA-224

HFD-344

HFD-340

HFR-NE250

HFR-NE250

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

MO:Sevka

CSO:L.Chen

r/d:RSKY:3/11/98

corrected:slk:3/11/98

**APPEARS THIS WAY
ON ORIGINAL**