



*Nighswander*

Food and Drug Administration  
Rockville MD 20857

MAY 27 1998

Prof. Marcel Châtel  
Hospital Pasteur  
30 Avenue de la Voie Romaine  
F-06002 Nice Cedex 1  
FRANCE

Dear Prof. Châtel:

On November 6-10, 1997, Doctors Gerald N. McGirl and 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. 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 and of the documents collected during the inspection, 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:

1. Consent forms should cover all of the elements required by 21 CFR 50.25(a), which is enclosed.
2. Observations required by the protocol such as respiratory rate, blood pressures, etc. should be made.
3. All study related papers should be identified so that it is clear to which subject they belong.
4. Hospital notes should capture a subject's clinical course.

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 our personnel during the inspection.

Sincerely yours,

David A. Lepay, M.D., Ph.D.  
Director  
Division of Scientific  
Investigations  
Office of Compliance  
Center for Drug Evaluation  
and Research

**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-PA150 DIB

HFR-PA150 BIMO Monitor

CFN:

Field classification: NAI

Headquarters classification:

1) NAI

2) VAI-no response required

3) VAI-response requested

4) OAI

If Headquarters classification is different classification,  
explain why: some deficiencies

Deficiencies noted:

inadequate consent form

inadequate drug accountability

failure to adhere to protocol

inadequate records

failure to report ADRS \_\_\_\_\_

other (specify)

r/d:RSKY:5/19/98

finald:slk:5/20/98

**APPEARS THIS WAY  
ON ORIGINAL**