

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

CLINICAL INSPECTION SUMMARY

DATE: April 4, 2000

TO: Robbin Nighswander, R. Ph., Regulatory Project Manager
Ranjit Mani, M.D., Clinical Reviewer
Division of Neuropharmacological Drug Products, HFD-120

THROUGH: Antoine El-Hage, Ph.D., Chief
Good Clinical Practice Branch II, HFD-47
Division of Scientific Investigations

FROM: Constance Lewin, M.D.
Good Clinical Practice Branch II, HFD-47
Division of Scientific Investigations

SUBJECT: Evaluation of Clinical Inspections

NDA: 20-823 (capsules) & 21-025 (liquid)

APPLICANT: Novartis Pharmaceuticals

DRUG: Exelon (rivastigmine tartrate)

CHEMICAL CLASSIFICATION: 1

THERAPEUTIC CLASSIFICATION: Standard Review

INDICATIONS: Treatment of mild to moderate dementia of the Alzheimer's type (NDA 20-823)
Treatment of Alzheimer's Disease (NDA 21-025)

CONSULTATION REQUEST DATE:

ACTION GOAL DATES: April 21, 2000 (NDA 20-823)
April 22, 2000 (NDA 21-025)

I. BACKGROUND:

Routine and directed clinical inspections were conducted in conjunction with the above-noted applications. Inspection results are noted below.

II. RESULTS (by protocol/site):

Name	City	State	Country	Assigned Date	Received Date	Classification
Chatel	Nice	--	France	10-22-97	04-22-98	VAI
Dal-Bianco	Vienna	--	Austria	10-29-97	02-05-98	NAI
Ripley	S. Yarmouth	MA	USA	06-26-97	12-09-97	VAI
Walicke/Jann	Atlanta	GA	USA	06-26-97	03-02-98	VAI

A. Protocol ENA B303

1. Site #1 (Chatel - Nice, France):

Twenty-nine (29) subjects were enrolled in this study at this site. This was a routine data audit, in which records from ten (10) subjects were reviewed. No Form FDA 483 was issued. However, in an information letter, the principal investigator was informed of findings regarding informed-consent inadequacies and inadequate recordkeeping.

Data appear acceptable.

2. Site #2 (Dal-Bianco - Vienna, Austria):

Thirty (30) subjects were enrolled in this study at this site. This was a routine data audit, in which records for eight (8) subjects were reviewed. No Form FDA 483 was issued. However, in an information letter, the principal investigator was informed of findings regarding protocol deviations and inadequate recordkeeping.

Data appear acceptable.

B. Protocol ENA B352

1. Site #1 (Ripley - South Yarmouth, MA)

Forty-six (46) subjects were enrolled in this study at this site. This was a routine data audit, in which twenty percent of subject records were reviewed. A Form FDA 483 was issued. In an information letter, the principal investigator was informed of findings regarding inadequate recordkeeping.

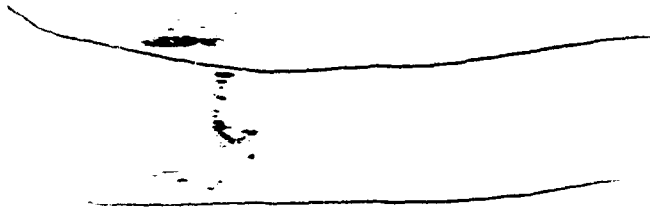
Data appear acceptable.

2. Site #2 (Walicke/Jann - Atlanta, GA)

Thirty-five (35) subjects were enrolled in this study at two sites in Atlanta, Georgia. Dr. Walicke was the original principal investigator; Dr. Jann subsequently took over those responsibilities. This was a routine data audit, in which records for six (6) subjects were reviewed. A Form FDA 483 was issued. In an information letter, Drs. Walicke and Jann were informed of findings regarding inadequate recordkeeping, failure to submit advertisement materials for IRB approval, failure to obtain IRB approval of protocol amendments in a timely fashion, and failure to report serious adverse events to the IRB in a timely fashion.

Data appear acceptable.

C. Protocols ENA B-351 & B-353



D. Protocol ENA B-356



**APPEARS THIS WAY
ON ORIGINAL**

Ena B-356

