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FEDERAL EXPRESS

OCT 14 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

Jill M. Rabin, M.D.
1554 Northern Boulevard
Manhasset, New York 11030

Dear Dr. Rabin:

You were inspected between May 9-23, 1997, by Thomas P. Hansen, an investigator with the Food and Drug Administration (FDA), New York District Office, Syosset Resident Post. The purpose of that inspection was to determine whether your activities as a clinical investigator for the investigational study of the

[REDACTED]
with applicable FDA regulations. This product is a device as that term is defined in section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Our review of the inspection report submitted by the district office revealed violations of Title 21, Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions and Part 50 - Informed Consent of Human Subjects. These items were listed as observations on the Form FDA-483, Inspectional Observations, which were presented to and discussed with you at the conclusion of the inspection. The following list of violations is not intended to be an all-inclusive list of deficiencies in the above referenced clinical study.

- 1) Failure to conduct an investigation in accordance with the investigational plan, conditions of approval imposed by the Institutional Review Board (IRB), the signed agreement with the sponsor, and applicable FDA regulations as required by 21 CFR 812.110(b).

Of the subject histories reviewed, 10 of 17 subjects failed to meet the protocol entry criteria. [REDACTED] had a history of a neurological deficit. Three subjects [REDACTED] were voiding greater than twice per night. [REDACTED] had recent pelvic surgery. [REDACTED] suffered from other types of incontinence. [REDACTED] had radical pelvic surgery. [REDACTED] were current smokers.

[REDACTED] did not receive the required 30-day urinalysis. [REDACTED] did not give informed consent before participating in the study. The adverse event (brown mucous discharge) by [REDACTED] was not reported to the sponsor.

There was no evidence that the reviewing institutional review board (IRB), Long Island Jewish Medical Center was notified about these ineligible patients and other protocol deviations. 21 CFR 812.150(a)(4) requires that all deviations from the protocol be reported to the sponsor and reviewing IRB.

- 2) Failure to obtain IRB approval as required by 21 CFR 812.110(a).

You failed to obtain IRB approval for an amended clinical protocol.

[REDACTED]

According to the IRB application packet criteria, clinical investigators are required to state and submit information about recruitment methods including advertisements with the protocol. You failed to submit and obtain IRB approval for two advertisements used in the subject recruitment.

- 3) Failure to ensure that proper informed consent is obtained as required in 21 CFR 812.100 and 21 CFR 50.

You did not obtain IRB approval for the informed consent document that you used during the study as stated in 21 CFR 50.27. Additionally, this unapproved document did not meet the requirements of 21 CFR 50.25 in that the consent form did not include specific information about subject's participation in the study beyond the 30 days.

- 4) Failure to keep accurate records of the receipt, use, or disposition of the investigational device as required by 21 CFR 812.140 (a)(2).

With the exception of two partial lists of devices shipped and received, the available records were inadequate to meet the requirements of this section.

- 5) Failure to maintain accurate, complete, and current records of each subject's case history and exposure to the device as required by 21 CFR 812.140 (a)(3).

Your subject inventory does not identify all subjects who continued in the study beyond 30 days nor did you maintain copies of the sponsor prescription registration forms completed by all subjects.

- 6) Failure to submit a final report to the reviewing IRB within three months after completion of the study as required by 21 CFR 812.150 (a)(6).

The last subject [REDACTED] completed the study on October 1, 1996; as of the date of the inspection, you had not submitted a final report to the IRB.

We have reviewed your June 17, 1997, letter responding to the FDA-483 addressed to the New York District Office. You acknowledged the seriousness of the violations and promised that efforts will be made to avoid recurrence. Your letter will be placed in our permanent record. Corrections may be verified during a future inspection.

This letter is not intended to be an all-inclusive list of your clinical study deficiencies. It is your responsibility to assure adherence to each requirement of the Act and regulations. This includes adequate and accurate record-keeping as well as the reporting of all adverse device events and protocol deviations.

If you have any questions or wish to make a further response, your correspondence should be directed to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch I (HFZ-311), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Kevin M. Hopson (301) 594-4720. A copy of this letter has been forwarded to the Food and Drug Administration, New York District Office. We request that in addition to the above, you send a copy of any additional correspondence to that office.

Sincerely,



for

Lillian J. Gill
Director
Office of Compliance
Center for Devices
and Radiological Health