

FEDERAL EXPRESSFood and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 21 1997

WARNING LETTER

Kevin F. Browne, Jr., M.D.
Watson Clinic
1600 Lakeland Hills Boulevard
Lakeland, Florida 33805

Dear Dr. Browne:

Between September 29 and October 9, 1997, you were visited by R. Kevin Vogel, an investigator with the Food and Drug Administration (FDA), Florida District Office. The purpose of that inspectional visit was to determine whether your activities as a clinical investigator for the investigational study of [REDACTED] complied 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. These items were observations on a Form FDA-483 which was 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 conditions of approval imposed by the Institutional Review Board (IRB) as required by 21 CFR 812.110(b).

Your IRB requires that a summary of side effects and untoward reactions be submitted in annual monitoring reports. The review of 21 subjects' records disclosed that three subjects experienced serious adverse events which were not reported to the IRB.

2) Failure to ensure that proper informed consent is obtained as required by 21 CFR 812.100 and 21 CFR 812.140(a)(3)(i) .

According to 21 CFR 50.25, informed consent shall include a description of the procedures to be followed. The possibility of angiographic examination being done during the 2-month post PTCA follow-up was not included. In addition, there was no documentation of informed consent for one subject.

3) Failure to ensure that an investigation is conducted in accordance with the investigational plan as required by 21 CFR 812.110.

Ten of 57 subjects enrolled in the study were ineligible in that they did not meet the inclusion criteria. In addition, one subject should have been excluded because of that subject's concurrent participation in another investigational (drug) study.

Other deviations from the investigational plan were disclosed in the report, including failure to perform required 2-month post [REDACTED] stress tests on two subjects.

4) 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)(ii).

There was a lack of documentation related to the study in that "Angiographic Physician Data Forms" were not completed for ten subjects. In addition, either [REDACTED], or both, were not recorded in 14 of 21 subjects' records reviewed.

5) Failure to maintain accurate, complete and current records relating to receipt, distribution and use of the study devices as required by 21 CFR 812.140(a)(2).

There was lack of inventory control of devices in that records documenting the names of all persons who received, used or disposed of each device were incomplete.

The above violations are not intended to be an all-inclusive list of deficiencies in your clinical study. It is your responsibility to ensure adherence to all requirements of the Act relevant to device clinical investigation or research.

Please advise this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent the recurrence of similar violations in current or future studies. Your failure to respond may result in further regulatory action without notice.

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A copy of this Warning Letter has been sent to the Food and Drug Administration, Florida District Office, 7200 Lake Ellenor Drive, Orlando, Florida 33805. Your response to this letter 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: L. Glenn Massimilla. We request that a copy of your response also be sent to The Florida District Office.

Please direct all questions concerning this matter to Mr. Massimilla at 301-594-4720, ext. 136.

Sincerely yours,



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