



NOV 7 1996

FEDERAL EXPRESS

WARNING LETTER

Mr. Peter J. Kramer
President/CEO
Suncoast Medical Group, Inc.
7401-114th Avenue
Suite 503-A
Largo, Florida 34643

Dear Mr. Kramer:

During June 10-18, 1996, Mr. Ernest A. Clausnitzer, an investigator from the Food and Drug Administration's (FDA) Florida District Office, visited your firm. The purpose of that visit was to conduct an inspection to determine whether your firm's activities as a sponsor/monitor of the investigational study for Suncoast Medical Group's [REDACTED] [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 Florida District Office raised significant questions about your conduct as the sponsor of this investigation. The inspection revealed violations of Title 21 Code of Federal Regulations (21 CFR), Part 813-Investigational Exemptions for Intraocular Lenses. The violations noted during the inspection were listed on form FDA-483, "Inspectional Observations," which was presented to and discussed with you at the conclusion of the inspection. The violations noted are as follows:

- 1) Failure to require investigators to return all reusable or unused supply of the [REDACTED] [21 CFR 813.45(b)].

[REDACTED] accountability for the following was lacking:

Investigator [REDACTED] There was no documentation to show the number of [REDACTED] shipped to [REDACTED] Ten [REDACTED] were [REDACTED]. The disposition of any remaining [REDACTED] is unknown.

Investigator [REDACTED] 38 [REDACTED] shipped; 5 [REDACTED] disposition of 33 [REDACTED] unknown.

Investigator [REDACTED] 37 [REDACTED] shipped; 11 [REDACTED] disposition of 26 [REDACTED] unknown.

Investigator [REDACTED] 73 [REDACTED] shipped; 35 [REDACTED] were [REDACTED] disposition of 38 [REDACTED] unknown.

- 2) Failure to adequately monitor the investigational study [21 CFR 813.46(a)].

Your firm failed to conduct periodic reviews of clinical investigators, to assure that the investigational plan was being followed and that data being submitted to your firm was accurate and complete.

Investigators were submitting incomplete case report forms and [REDACTED] without IRB approval and signed investigators' agreement forms.

IRB approval/disapproval statements were not available for the Yadana facility, located in Montego Bay, Jamaica, where at least [REDACTED] were [REDACTED] and the Eldemire Hospital, located in Montego Bay, Jamaica, where at least [REDACTED] the [REDACTED] in patients in foreign countries was not permitted under your firm's IDE.

- 3) Failure to obtain an Investigator Agreement from an investigator before participation in the study [21 CFR 813.43(b)].

The Investigator Agreement between Suncoast and Investigator [REDACTED] was signed on July 11, 1991, yet the investigator performed his first [REDACTED] on May 21, 1990.

The above violations are not intended to be an all-inclusive list of deficiencies that may have existed in the clinical studies for your firm's [REDACTED].

We are aware of your firm's July 1, 1996, request to the Office of Device Evaluation to terminate your IDE.

Within fifteen (15) working days of receipt of this letter, please provide this office with written documentation of any other specific steps you have taken or will be taking to bring

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any future studies into compliance. Your failure to respond may result in regulatory action being initiated without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Your response 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 II, 2098 Gaither Road, HFZ-312, Rockville, Maryland 20850 Attention: Viola Sellman. A copy of this letter has been sent to the Florida District Office, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809. We request that you send a copy of your response to that office.

Sincerely yours,



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

cc:

Thomas De Balla
Executive Vice President
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