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JUL 19 2000

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville MD 20850**WARNING LETTER**
Via Federal Express

Joseph W. Spadafora, D.O.
St. Lucy's Outpatient Surgery Center
21275 Olean Boulevard
Port Charlotte, Florida 33952

Dear Dr. Spadafora:

The purpose of this Warning Letter is to inform you of objectionable conditions found during a Food and Drug Administration (FDA) inspection conducted at your clinical site and to request a prompt reply. The inspection took place during the period of May 15 and June 1, 2000, and was conducted by Ms. Shari J. Hamilton, an investigator from FDA's Florida District Office. The purpose of the inspection was to determine if your activities as a clinical investigator with [REDACTED] [REDACTED] comply with applicable FDA regulations. [REDACTED] are devices as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval Applications (PMA), and Premarket Notifications [510(k)] are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report submitted by the district office revealed serious violations of requirements of Title 21, Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions, Part 50 - Protection of Human Subjects, and Section 520(g) of the Act. The deviations noted were listed on a form FDA-483, "Inspectional Observations," which was issued at the conclusion of the inspection and discussed with you. Deviations noted include the following:

Failure to conduct the study according to the investigational plan [21 CFR 812.100 and 812.110(b)].

You included several subjects in the study in violation of the inclusion/exclusion criteria. Moreover, you did not perform required post-operative follow-ups for all subjects or they were performed outside of the scheduled timeframes; you did not take [REDACTED] and [REDACTED] photographs at all required visits; and you did not measure [REDACTED] at all post-operative visits.

Failure to maintain complete records of documents evidencing informed consent [21 CFR 812.140(a)(3)(i)]

You were unable to locate the initial informed consent documents for 6 study subjects and informed consent documents for surgery on the second eye for 3 subjects.

Failure to maintain institutional review board (IRB) approval of the study (21 CFR 812.64).

You treated at least 2 subjects during a lapse in IRB approval of the study.

Failure to maintain accurate and complete case report forms for all study subjects [21 CFR 812.140(a)(3)].

You did not have the required case report forms (CRFs) for at least 4 study subjects and review of the CRFs available revealed discrepancies when compared with the source documents. Moreover, you were not able to identify the total number of subjects treated during the study. Your subject files did not agree with either summary sheets you provided or those from the sponsor.

Failure to maintain records of correspondence with the reviewing IRB and with the sponsor [21 CFR 812.140(a)(1)].

You provided no records of visits from or correspondence with the sponsor during the course of the study. You failed to have the most recent copy of the protocol and could not document that the sponsor had discussed study changes with you verbally. You submitted no progress reports to either the IRB or sponsor as far as your records or theirs could produce. IRB correspondence you located consisted mainly of response letters from the IRB.

The deviations listed above are not intended to be an all-inclusive list of deficiencies that may exist in your clinical study. It is your responsibility as a clinical investigator to ensure that an investigation is conducted according to the signed agreement, the investigational plan, and applicable FDA regulations.

A copy of a [REDACTED] article, dated Sunday, December 26, 1999, with an accompanying advertisement, was included in the inspection report (copy enclosed). The article discusses several medical devices and related procedures. Some if not all are or were investigational. 21 CFR 812.7 prohibits claims that an investigational use of a medical device is safe and effective. Advertisements for investigational devices are limited to study subject recruitment and the article does not fall into this category. Moreover, recruitment information is considered part of the informed consent process for study subjects and must be approved for use by the reviewing IRB. You could produce no records that the reviewing IRB had reviewed this article.

The accompanying advertisement is for [REDACTED], a [REDACTED] procedure according to the advertisement. Presently no [REDACTED] has been approved for use in the procedure described. Therefore, if the [REDACTED] used in this

procedure is an approved product, this would be an "off label" use of that product. While FDA does not regulate the practice of medicine, you cannot advertise the "off label" use of approved products. If the [REDACTED] used is investigational, you cannot advertise except for the recruitment of study subjects, as explained in the previous paragraph.

Your study with the [REDACTED] is on-going. The inspection report notes that corrective actions were promised. Please inform us, within 15 working days of receipt of this letter, of the actions you have instituted to correct the deviations noted and to prevent their recurrence. Please send your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch II (HFZ-312), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Jean Toth-Allen, Ph.D. Failure to respond could result in further regulatory action without additional notice, including initiation of investigator disqualification procedures.

A copy of this letter has been sent to FDA's Florida District Office, 555 Winderley Place, Suite 200, Maitland, Florida 32751. We request that a copy of your response also be sent to that office.

If you have any questions, feel free to contact Jean Toth-Allen, Ph.D. at (301) 594-4723, ext. 141.

Sincerely yours,



Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure

cc:

[REDACTED] (purged copy)
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

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William Lloyd, M.D., Chair (purged copy)
The Institutional Review Board
Clinical Research of Colorado Springs
12045 Calle Carvo
Colorado Springs, Colorado 80926