



JUL 2 2004

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Archibald S. Miller, III, M.D., F.A.C.S.
Cosmetic and Reconstructive Surgery of Tulsa
6585 South Yale, Suite 315
Tulsa, Oklahoma 74136-8316

Dear Dr. Miller:

This Warning Letter informs you of objectionable conditions revealed during a Food and Drug Administration (FDA) inspection of your clinical site. This letter also discusses your written response to the noted violations and requests that you implement prompt corrective actions. Mr. Joel Martinez and Ms. Janice M. Hickok, investigators from FDA's Dallas District Office, conducted the inspection from December 8 through December 12, 2003. The purpose of the inspection was to determine whether your activities and procedures as a clinical investigator relating to investigational studies with significant risk devices complied with applicable FDA regulations. The product used in [REDACTED] and the product implanted in patients known as [REDACTED] are devices as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S. C. 321(h)].

The FDA conducted the inspection under a program designed to ensure that data and information contained in applications for Investigational Device Exemptions (IDEs), Premarket Approvals (PMAs), and Premarket Notification (510(k)) submissions are scientifically valid and accurate. This program also ensures that human subjects are protected from undue hazard or risk during scientific investigations.

Our review of the inspection report prepared by the Dallas District Office revealed serious violations of the requirements of section 501(f)(1)(B) and 502(o) of the Food, Drug and Cosmetic Act and the regulations under Title 21, Code of Federal Regulations (21 CFR), Part 812-Investigational Device Exemptions. Additionally, we have reviewed your December 22, 2003, response to the deficiencies listed on the Form FDA 483, "Inspectional Observations," which Mr. Martinez and Ms. Hickok presented and discussed with you and [REDACTED] at the conclusion of the inspection on December 12, 2003.

We agree with your response to the first item in the FDA-483 that the [REDACTED] is not under an approved investigational

device exemption (IDE), however, contrary to your assertion, it is not a custom device. A detailed discussion of your use of the [REDACTED] follows:

In your written response to the FDA-483, "Inspectional Observations" dated December 12, 2003 you asserted that these devices are custom devices. This letter provides an explanation of the authorities governing custom devices and will also address issues raised in your written response and your exhibits to the FDA.

Federal law requires that manufacturers obtain approval or clearance from the FDA before new devices may be implanted in human subjects. FDA approval is required before these devices may be offered for sale or use to clinical investigators conducting research or to physicians. This helps protect the public health by ensuring that new medical devices are shown either to be safe and effective or to be substantially equivalent to other devices legally marketed in this country. The current inspection revealed you treated approximately [REDACTED] patients with unapproved significant risk medical devices without the knowledge or approval of the FDA, without IRB oversight, and without an approved IDE. Consequently, these devices are adulterated under section 501(f)(1)(A) of the Act. Your product is misbranded under section 501(o) of the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

Your statement regarding the use of custom devices indicates a fundamental misunderstanding of the custom device provisions of the Act and implementing regulations. The custom device exemption of section 520 (b) of the Act extends a limited exemption from the premarket approval requirements outlined in section 515 of the Act to devices that meet a narrow and specific set of statutory criteria. In addition, by regulation FDA has exempted custom devices from IDE requirements. [21 CFR 812.2(c)(7)].

The IDE regulation does not exempt from its requirements a broader category of devices than 520(b) of the Act exempts from the requirements of a PMA. Consequently a device that could not qualify for a custom device exemption under section 520(b) also can not qualify for an exemption from IDE requirements under 21 CFR 812.2(c)(7).

The [REDACTED] distributed by [REDACTED] and developed by you do not meet the criteria for a custom device and, therefore, are not exempt from compliance with the premarket approval or investigational device exemption regulations. For example, these mammary implants are not intended for use by an individual patient named in a physician's order and made in a specific form for that patient. Furthermore, they were not intended to meet a particular unique practice need of you or other participating physicians at Cosmetic and Reconstructive Surgery at Tulsa, Saint Francis Hospital, and Saint John Medical Center [21 CFR 812.3(b)(5)].

In fact, there are saline-filled mammary implants currently available for breast augmentation in women 18 years or older and for breast reconstruction in women of all ages. Any significant risk class III device remains subject to the requirements of an IDE or PMA under the Act. The custom device provision was not meant to allow the circumvention of otherwise applicable provisions under the Act.

Continued implantation of these devices will be considered by FDA to be knowingly violating the Food, Drug, and Cosmetic Act. Your written response should identify all human subjects by name, address and date of implantation who received the [REDACTED] [REDACTED] or any other unapproved device. To protect the rights and welfare of the human subjects you implanted, we recommend you develop a corrective action plan that includes notification of each recipient by certified mail that they were implanted with an unapproved device, who to contact in the event of an emergency and to report adverse events. Your corrective action plan should be submitted to this office prior to implementation as well as copies of all letters sent to implant recipients.

We agree that you reported the adverse event to the sponsor [REDACTED], [REDACTED] as indicated in the second item of your response to the FDA 483. This documentation satisfies the reporting of the adverse event of subject [REDACTED] [REDACTED].

However, we disagree with your assertion regarding your record retention related to the clinical investigation, which you believed ended after two years to the date of the Site Termination Notice from [REDACTED]. The Site Termination Notice from [REDACTED], dated November 30, 2000, requires you to retain the records under the conditions which represent the latest date, that is, the approval of the PMA. Under 21 CFR 812.140(d), investigators' records for studies of devices must be retained for two years after the later of either of the following dates: the date the investigation is terminated or completed; or the date that the records no longer are required to support a premarket approval application or a notice of completion of a product development protocol. Because the premarket application has not been approved by the FDA, you must retain your records relating to the clinical investigation.

The deviations cited above are not intended to be an all-inclusive list of deficiencies at your site. As a clinical investigator, it is your responsibility to ensure that investigations that you participate in are conducted in accordance with applicable FDA regulations.

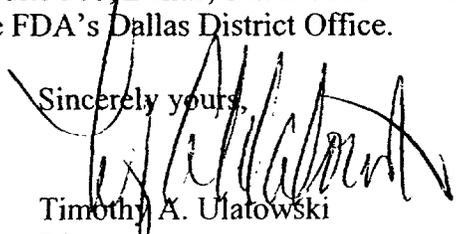
Within 15 days working days, you must respond to this letter in writing. You should be aware that FDA considers your actions to be serious violations of the law and may result in FDA taking regulatory action without further notice to you. Failure to respond can result in further regulatory action without further notice.

In addition, please provide a list of your current investigational studies and include the name of the study sponsor and the date of IRB approval.

You should direct your response 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), 2094 Gaither Road, Rockville, Maryland 20850. Attention: Kevin M. Hopson, MBA, Consumer Safety Officer. Please direct all questions concerning this matter to Mr. Hopson at (301)594-4720, extension 128.

A copy of this letter has been sent to the Food and Drug Administration, Dallas District Office, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204. We request that a copy of your response also be sent to the FDA's Dallas District Office.

Sincerely yours,



Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: PURGED COPIES

Saint Francis Hospital
Institutional Research Ethics Board
6161 South Yale Avenue
Tulsa, Oklahoma 74136

Saint John Medical Center
Institutional Review Board
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Tulsa, Oklahoma 74104