



WARNING LETTER
Via Federal Express

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

OCT 23 2000

R. McIntyre Bridges, M.D.
Bridges to Beauty Center for Cosmetic Surgery
4300 Youree Drive, Suite 300
Shreveport, Louisiana 71105

Dear Dr. Bridges:

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 July 25-27, 2000, and was conducted by Mss. Barbara D. Wright and Carolyn E. Barney, investigators of FDA's New Orleans District Office.

The purpose of the inspection was to determine if your activities as a clinical investigator in the [REDACTED] complied with applicable FDA regulations. [REDACTED] is a device as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

In addition, the inspection was conducted under a program designed to ensure that data and information contained in the requests for Investigational Device Exemptions (IDE), Premarket Approval Applications (PMA), and Premarket Notifications [510(k)] are scientifically valid and accurate, and that human subjects are protected from undue hazards or risks during the course of the clinical study. The clinical study supported PMA [REDACTED]

Our review of the inspection reported submitted by the New Orleans District revealed serious violations of requirements of Title 21, Code of Federal Regulations (21 CFR), Parts 50 – Protection of Human Subjects and Part 56 – Institutional Review Boards. The deviations noted were listed on a Form FDA-483 "Inspectional Observations," which Mss. Wright and Barney presented and discussed to you at the conclusion of the inspection. The deviations noted included the following:

1. Failure to obtain informed consent per 21 CFR 50.20.

You enrolled [REDACTED] subjects in the clinical study after the IRB terminated the study and before the IRB resumed study approval. These subjects did not receive legally effective informed consent.

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2. Failure to obtain IRB approval per 21 CFR 56.103.

You failed to obtain IRB approval for changes or deviations in the study protocol. There were, at least, [REDACTED] instances where subjects were implanted with the devices filled greater than the labeled volumes.

In addition, we note that you failed to follow the study protocol in that you did not report all adverse events to the sponsor and the IRB. [REDACTED] subjects' files reviewed by FDA investigators contained unreported adverse events.


The above deviations are not intended to be an all-inclusive list of deficiencies that may exist in the clinical study. Please acknowledge receipt of this letter within 15 working days, including documentation of any specific step you have taken or will take to correct these violations and prevent the recurrence of similar violations in current and future studies.

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 I (HFZ-311), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Kevin M. Hopson. Failure to respond to this letter could result in further regulatory action without further warning.

A copy of this letter has been sent to FDA's New Orleans District Office, 6000 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. We request that you send a copy of your response to this office.

If you have any questions, feel free to contact Mr. Kevin Hopson at (301) 594-4720, extension 128.

Sincerely yours,


for Larry D. Spears

Acting Director
Office of Compliance
Center for Devices and Radiological Health

cc: Mr. John C. Hutchison (purged)
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