



AUG 14 1997

Food and Drug Administration
Rockville MD 20857

Via Federal Express

WARNING LETTER

David Dulaney, M.D.
Barnet Dulaney Eye Center
4800 North 22nd Street
Phoenix, Arizona 85018

Dear Dr. Dulaney:

The purpose of this letter is to warn you that your [REDACTED] system (the [REDACTED] located at the Barnet Dulaney Eye Center in Mesa, Arizona, may not be used to treat patients beyond the conditions of approval of your investigational device exemption (IDE). Any use of the [REDACTED] beyond the terms of the FDA-approved IDE is in violation of federal law, 21 U.S.C. § 351(f)(1)(B). As discussed further below, inspection of your facility by the United States Food and Drug Administration (FDA) reveals that you have used the [REDACTED] in a manner that does not comply with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and FDA's IDE regulations.

Background

On December 27, 1996, in a letter received by FDA on January 8, 1997, you submitted an application for an IDE for evaluation of an [REDACTED] for use in [REDACTED]. In a letter dated February 7, 1997, FDA granted conditional approval for you to begin your investigation, after obtaining Institutional Review Board (IRB) approval and submitting certification of that IRB approval to FDA. Your [REDACTED] investigation was limited to correct [REDACTED] of [REDACTED], with or without [REDACTED]. It was also limited to one (1) institution and 100 subjects. Moreover, you were told to respond to a list of deficiencies contained in FDA's letter within 45 days of the date of the letter.

By letter dated March 24, 1997, Dr. Guy M. Kezirian, of SurgiVision® Consultants, Inc., attempted to respond on your behalf to the deficiencies cited in the February 7 letter. In FDA's April 24, 1997, response to Dr. Kezirian, you were told that your application remained conditionally approved because your supplement did not adequately address two of the deficiencies cited in FDA's February 7 letter. You were told you could continue your investigation provided you had obtained IRB approval and submitted certification of that approval to FDA. Your investigation remained limited to one (1) institution and 100 subjects. Response to the remaining deficiencies was to be in 45 days of the date of that letter.

In a letter dated May 30, 1997, you notified FDA that you had secured the assistance of Dr. Barbara Fant, Clinical Research Consultants, Inc., and Mr. Arthur Jackson, The Arthur Jackson Group. You also requested a 45 day extension for submission of a response to the deficiencies cited in the April 24, 1997, letter. FDA granted your request in a letter dated June 10, 1997, and again reminded you

that IRB approval was required for continuation of your investigation and that your investigation remains limited to one (1) institution and 100 subjects.

On July 21, 1997, Dr. Barbara Fant submitted IDE Supplement 3 on your behalf. It is presently under review.

On July 29, 1997, FDA contacted the Barnet Dulaney Eye Center by telephone to notify you that, based on the results of FDA's investigations, we believe that you have used your [REDACTED] in violation of the conditions of approval of your IDE and the IDE regulations and that you have used the entire allotment of 100 subjects allowed to be treated under your IDE. Thus, FDA requested that, if you were treating patients with your [REDACTED] you cease doing so immediately. FDA followed the telephone call with a letter dated July 31, 1997. As FDA requested, on August 1, 1997, you provided FDA with a written statement that, as of the close of business on July 29, 1997, the [REDACTED] was no longer being used and would not be used again "until there is an approved IDE supplement in effect for that [REDACTED] that allows treatment of additional subjects."

FDA's Inspection of the Barnet Dulaney Eye Center

On June 5 and 6, 1997, FDA inspected the Barnet Dulaney Eye Centers in Phoenix and Mesa, Arizona and reviewed records of patients treated with the [REDACTED]. The FDA inspection revealed the following:

- You have not obtained IRB review and approval for your clinical investigation. The regulations pertaining to IDEs, Title 21 Code of Federal Regulations (21 CFR) Part 812, require that a clinical investigator obtain IRB approval prior to initiating an investigation. See 21 CFR 812.110(a). You acknowledged this requirement in your IDE application and assured the agency that "IRB approval will be obtained prior to enrolling patients in this study..." IDE application, p. 17. In addition, FDA's February 7, 1997, conditional approval letter stated that you could begin your investigation only "after you have obtained...IRB approval and submitted certification of approval to FDA." Your study is considered to have been initiated as of the date of the conditional approval, February 7, 1997. Between February 7 and June 6, 1997, you treated at least 588 patients with your [REDACTED] even though you had not received IRB approval.
- You have exceeded the 100 patient limit of your conditional approval, having treated 588 patients since February 7, 1997. A clinical investigator is responsible for ensuring that an investigation is conducted according to conditions of approval imposed by FDA. See 21 CFR 812.110(b).
- You have not obtained IRB approval for your informed consent form. It is the responsibility of the clinical investigator to ensure that informed consent is obtained in accordance with FDA regulations for the Protection of Human Subjects. See 21 CFR 812.100 and 21 CFR Part 50.

- Properly signed and dated investigator agreements have not been obtained for all investigators involved in the study. FDA's regulations require investigators to conduct an investigation in accordance with a signed investigator agreement. See 21 CFR 812.11 and 812.43(c).
- Your investigational device does not bear the proper labeling. Specifically, your investigational device fails to bear a label stating, "CAUTION---Investigational Device, Limited by Federal (or United States) law to investigational use." See 21 CFR 812.5(a).

The violations listed above are not necessarily all-inclusive. Moreover, they are based on observations made during FDA's June 1997 inspection of your facility, and the concerns they raise are separate from, and in addition to, the deficiencies noted in FDA's April 24, 1997, letter to you.

Violations of the FD&C Act and FDA's Regulations

The Barnet Dulaney [REDACTED] is an unapproved Class III device under Section 513 of the FD&C Act. We acknowledge that you have agreed to cease treating patients with the [REDACTED] unless and until there is an approved IDE supplement in effect for your [REDACTED] that allows treatment of additional subjects. You should be aware that if you resume treating patients without receiving approval from FDA, your conduct would violate the FD&C Act and FDA regulations.

Within 15 working days of your receipt of this letter, please notify this office of what actions, in addition to those specified in your August 1, 1997, letter, you are taking to bring your device into compliance with the requirements of the FD&C Act. Please send your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, 2098 Gaither Road, Rockville, Maryland 20850, Attention: Jean Toth-Allen, Ph.D.

A copy of this letter has been forwarded to our Los Angeles District Office 19900 MacArthur, Suite 300, Irvine, California 92715. We request that a copy of your response be sent to that office.

We want you to be aware that failure to comply with the law may result in further regulatory action against you or the device by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties.

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If you have any questions, you may contact Jean Toth-Allen at (301) 594 - 4723, ext. 141.

Sincerely yours,



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