



JUL - 9 2001

WARNING LETTERFood and Drug Administration
2098 Gaither Road
Rockville MD 20850via Federal Express

Mr. David Amar
President
SciOptic International
238 North Highland Avenue
Suite # 6
Ossining, New York 10562

Dear Mr. Amar:

During the period of March 21-27, 2001, Mr. Thomas P. Hansen and Mr. L. Glenn Massimilla, Investigators with the U. S. Food and Drug Administration (FDA), New York District Office, conducted an inspection at SciOptic International. The purpose of that inspection was to determine whether SciOptic's activities as the sponsor/ monitor of any investigational studies of the [REDACTED] complied with applicable FDA regulations. This product is a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our review of information from this inspection revealed violations of FDA regulations contained in Title 21, Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions. The findings of FDA's inspection at the sponsor/monitor level were listed on the form FDA-483, "Inspectional Observations," which was presented to you, and discussed with you a [REDACTED] at the conclusion of the inspection.

The following enumeration and discussion of violations and deviations from the regulations is not intended to be an all-inclusive list of problems encountered during our review.

I. Failure to prepare and submit complete, accurate, and timely reports of the progress of the investigation to FDA -- [21 CFR 812.150(b)(5)]

Your firm failed to prepare and submit progress reports to FDA at regular intervals, or at least yearly. The above-referenced IDE submission was "Conditionally Approved" on February 4, 1998. At that time, FDA provided SciOptic guidance concerning the firm's responsibility as a sponsor of a significant risk device investigation. In that FDA had not received a progress report by October 7, 1999, FDA's correspondence to SciOptic on that date requested that your firm fulfill the IDE reporting requirements. Your firm's response to FDA, dated November 22, 1999, did not adequately address FDA's request.

In a letter dated May 22, 2000, FDA requested that SciOptic submit a progress report within 45 days. During August 2000, [REDACTED] stated to FDA that SciOptic planned to discontinue clinical studies under this IDE. Subsequently, in a letter dated September 26, 2000, FDA requested that SciOptic submit a final report within 45 days. As of March 21, 2001, SciOptic had not submitted any of the required reports to FDA.

2. Failure to maintain accurate, complete and current records relating to an investigation including all records of the receipt, shipment and disposition of the investigational device -- [21 CFR 812.140(b)(2)]

The sponsor is required to maintain such records during the investigation and for two years after the date the investigation is terminated or completed. To the extent that your firm maintained any records of investigational device distribution (i.e. shipping records), you did so for only the previous ninety days. You acknowledged that the firm has shipped investigational devices to practitioners (optometrists) for several years.

Furthermore, the firm has been receiving the investigational device, the [REDACTED] for several years, and yet it has no records documenting receipt. When FDA requested that SciOptic retrieve any related documents from the supplier ([REDACTED]), SciOptic reported that these records were not readily retrievable.

As a result of the failure to have effective policies and procedures, records were not properly managed. FDA could not determine the number of investigational devices received or the number distributed by SciOptic, either before, or subsequent to, IDE approval.

3. Failure to maintain control of devices in that the sponsor shipped investigational devices to practitioners other than qualified investigators participating in the investigation -- [21 CFR 812.43(b)]

Nine practitioners were listed in the IDE submission as clinical investigators, without signed investigator agreements as of March 21, 2001. The only available accountability records, for the previous ninety days, indicate that SciOptic supplied five of these nine "potential" investigators with devices. Furthermore, review of the sponsor's shipping records disclosed that a total of 54 practitioners at 57 sites received investigational devices from the firm. None of these practitioners were qualified investigators participating in the investigation.

4. Failure to obtain signed agreements from each investigator participating in the investigation -- [21 CFR 812.43(c)]

Nine practitioners were listed in the IDE submission as clinical investigators. None had signed investigator agreements with the sponsor as of March 21, 2001.

5. Failure to ensure proper labeling of the investigational device -- (21 CFR 812.5)

Based on inspectional observations, the device or its immediate packaging did not bear a label containing the following statement: "CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use."

We acknowledge that FDA received a letter from SciOptic, Inc., dated March 27, 2001, requesting withdrawal of the IDE by the sponsor and the IDE has been withdrawn. Nonetheless, FDA remains concerned about the possibility that SciOptic may continue to import and distribute the [REDACTED] outside of the context of an approved IDE clinical study conducted in accordance with the requirements of 21 CFR 812.

Given that the IDE for the [REDACTED] has been withdrawn, you do not have an order from the FDA allowing you to distribute the device for overnight wear. Therefore, you are prohibited from introducing this device into interstate commerce for overnight wear until such approval is granted. Introducing the [REDACTED] into interstate commerce could misbrand your device within the meaning of Section 502(o) of the Federal Food, Drug, and Cosmetic Act (the Act), in that you have failed to obtain approval of a premarket approval application (PMA) prior to offering this device for sale in interstate commerce. Further, because this device has not yet been found safe and effective through the review of valid scientific evidence included in a PMA submission, this device may also be adulterated within the meaning of Section 501(f)(1)(B) of the Act, in that it has been offered for sale in interstate commerce for the first time after May 28, 1976, thereby statutorily classifying it as a class III device, and it fails to have, as required under Section 515(a), an approved application for premarket approval (PMA), and it is not exempt from such requirement under an investigational device exemption (IDE) as required under Section 520(g).

SciOptic has contended that the [REDACTED] could be considered as a "custom device" within the meaning of 21 CFR 812.3(b). FDA has previously informed you that the [REDACTED] is not a custom device as it does not meet the necessary criteria found in section 520(b) of the Act, or in 21 CFR 812.3 of the implementing regulations. In addition, FDA has previously viewed any software specifically intended for use in designing contact lenses as a medical device and subject to premarket notification [510(k)] requirements.

It is your responsibility to ensure adherence to each requirement of the Act and regulations. Within 15 days of receipt of this letter, please provide this office with written documentation of the specific steps your firm has taken or will take to discontinue distribution of the above-referenced device in the future. FDA may verify that corrective actions have been implemented during a future inspection of your firm.

Your response should be directed to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring (HFZ-311), 2098 Gaither Road, Rockville, Maryland 20850. Attention: Ms. Pamela Reynolds. A copy of this letter has been sent to the Food and Drug Administration's New York District Office, 158-15 Liberty Avenue, Jamaica, New York, 11433. Attention: Mr. Jerome G. Woysner. We request that a copy of your response also be sent to Mr. Woysner.

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If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your failure to respond may result in regulatory action without further notice.

Please direct questions concerning this matter to Ms. Pamela Reynolds at (301) 594-4720, extension 155.

Sincerely yours,



Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health