



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Federal Express

JAN 22 1999

WARNING LETTER

Jeffrey Dann, M.D.
NEBL, Inc.
44 Terrace Drive
Worcester, Massachusetts 01609

Dear Dr. Dann:

During the period of October 6-20, 1998, Sandra P. White, an investigator with the U.S. Food and Drug Administration (FDA), New England District Office, inspected your facility. The purpose of that inspection was to determine whether the activities of NEBL, Inc., as the sponsor of the investigational study of the Re/Stor (Confidence) female incontinence device (510(k) K971259 and IDE G960090), complied with applicable FDA regulations. This product is a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Our review of the inspection report, as well as the inspection reports for the audits of participating clinical investigators revealed violations of Title 21, Code of Federal Regulations (21 CFR), Part 812, Investigational Device Exemptions. The findings from your inspection were listed on form FDA 483, Inspectional Observations, which was presented to and discussed with you at the conclusion of the inspection.

The following list of violations is not intended to be an all-inclusive list of the problems encountered during our reviews. We have listed FDA's inspectional findings related to deficiencies in your role as sponsor of the referenced investigational device study so that you may correct your study monitoring procedures.

- (1) Failure to ensure proper monitoring of the clinical investigation as required in 21-CFR 812.40.

Monitoring visits and telephone contact with the clinical sites were not documented for this study. You failed to have written procedures in place to ensure adequate monitoring of studies.

- (2) Failure to ensure investigator compliance as required by 21 CFR 812.46.

Violations of the regulations were found at the clinical site of [redacted] and [redacted] including the failure to maintain accurate, current, and complete study records. There are no summary reports from the clinical investigators. In addition, there

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were deviations from the study protocol ([REDACTED]), (4 words) and failure to report those deviations and protocol changes to the respective IRBs. Information in the 510(k) submission to FDA indicated that alteration of the device was not permitted. Nebl Inc. did not institute actions during the study to achieve investigator compliance.

- (3) Failure to provide accurate, complete, and current information as required by 21 CFR 812. 140(b) (1-2).

You failed to maintain documentation of the notification to the clinical sites that the device risk status changed from non-significant risk to significant risk. In addition, there is no documentation that you notified the affected Institutional Review Boards and study sites of the FDA approved inclusion/exclusion criteria changes. Study records for device accountability were either non-existent or poorly organized. Your response indicates that you have corrected your device accountability records and that you have now notified clinical sites of the revised risk status of the device. These actions were taken after the FDA investigator completed the inspection.

While none of the previously listed violations prevented the clearance of your premarket notification, it is your responsibility to ensure adherence to each requirement of the Act and regulations. We acknowledge your written response dated November 2, 1998, describing some of the corrective actions that your firm is now implementing. However, within 15 days, of receipt of this letter, please provide this office with written documentation of the specific steps, including your current monitoring procedures and any other steps that you have taken to correct these violations to prevent the recurrence of similar violations in current and future studies.

Your response should be directed 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: Mr. David Kalins. We request that a copy of any correspondence be sent to the Food and Drug Administration's New England District Office, One Montvale Avenue, Stoneham, Massachusetts 02180. Should you require additional time to respond, or have any questions concerning this matter, please contact Ms. Alice Rozema (301) 594-4720, ext. 131.

Sincerely yours,



for

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