



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m3949n

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

June 30, 2000

Our Reference No. 2953140

John G. Schulte, President and CEO
Somnus Medical Technologies, Inc.
285 North Wolf Road
Sunnyvale, CA 94086

WARNING LETTER

Dear Mr. Schulte:

During an inspection of your firm located in Sunnyvale, CA from March 21, 2000 through April 25, 2000, our investigator determined that your firm manufactures somnoplasty devices for the treatment of upper airway disorders. These are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above inspection revealed that the devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packaging, storage, or installation are not in conformance with the Quality System Regulation as specified in Title 21, *Code of Federal Regulations* (CFR) parts 820 as follows:

1. Management with Executive Responsibility at your firm failed to ensure that an adequate quality system has been established and maintained as required by 21 CFR 820.20. For example:

You have failed to assure that nine (9) out of thirty-nine (39) corrective actions identified in response to the April, 1999 FDA audit were completed. In addition, you have failed to assure that fourteen (14) out of approximately twenty-eight (28) corrective actions were completed within your established timeframes and there is no documented justification

for the delay. Your response dated May 16, 2000 states that the original response to the April 1999 FDA inspection promised corrective actions that were inappropriate, not clearly defined, or went beyond what was practical or reasonable to address. The May 16, 2000 response also states that the personnel who originally developed the corrective action plan lacked the necessary experience. It is management's responsibility to assure that adequate resources, including trained personnel, are available to meet the requirements of the Quality System Regulation. It is the duty of Management with Executive Responsibility to review and assure the suitability and effectiveness of the quality system, including corrective actions to known quality problems. Other examples of your failure to exercise executive responsibility are discussed below.

2. You have failed to establish, maintain, and follow procedures for implementing corrective and preventive actions, including the requirements of analyzing processes and sources of quality data to identify existing and potential causes of nonconforming product and other quality problems as required by 21 CFR 820.100. For example:

The corrective actions initiated in response to the April, 1999 FDA inspection, a source of quality data, were not entered into your Corrective and Preventive Action system.

You failed to identify the lack of tolerances for the functional test requirements during software validation as a potential quality problem and no corrective action was taken.

The software validation performed in response to the April 1999 FDA inspection was incomplete and failed to meet the pre-determined specifications as referenced in the validation protocol.

Your corrective action to the complaint handling system failed to assure that complaints are handled in a timely and effective manner. Our inspection found that 17 of 23 complaints received before December 31, 1999 and not closed by March 21, 2000 had no activity for three months. In addition, the PER database that you utilized to handle complaints allow for certain complaints to be excluded from trend reports.

Additionally, our investigator found that you had received a report indicating that your device may have contributed to or caused a serious injury. You failed to report this incident to FDA. We acknowledge your response in which you declare that you have retrospectively filed a report with FDA. Failure to submit required information to the Food and Drug Administration as specified by the Medical Device Reporting regulation

may result in your devices being misbranded within the meaning of section 502(t)(2) of the Act.

We acknowledge that you have submitted to this office written responses, dated May 16, May 22, and June 1, 2000, concerning our investigator's observations noted on the form FDA-483. We also acknowledge meeting with members of your company on June 8, 2000 to discuss the investigator's observations. Although your responses indicate that corrective measures have been undertaken, they do not completely address the deficiencies noted with your management and corrective and preventive action systems. For this reason the adequacy of your response cannot be fully evaluated. We request that these materials be provided to our office when the tasks have been completed. A reinspection will be necessary to assure that your corrections are adequate.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your manufacturing and quality system. You are responsible for investigating and determining the causes of the violations identified by FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submission for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates for Products to Export will be approved until the violations related to the subject devices have been corrected.

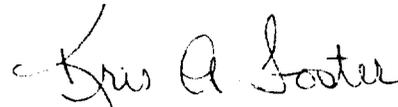
In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance for Class III devices for which a 510(k) has been submitted, and issue Certificates to Foreign Governments for products manufactured at your facility, we are requesting that you submit to this office a certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality system relative to the requirement of the device GMP regulation (21 CFR 820). This should be completed within ninety (90) days of receipt of this letter. You should also submit a copy of the consultant's report, and certification by your establishment's CEO/President that he has reviewed the consultant's report and that your establishment has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California 94502-7070, Attention: Russell A. Campbell, Compliance Officer.

Sincerely,



Kris A. Foster
Acting Director
San Francisco District

Enclosures:

FDA 483
CDRH, OC Industry Letter No. 2, Selecting a Consultant