HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

g1113d

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

April 9, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
CIN-WL-01-600

Donna M. Richardson
President/Chief Operating Officer
NeuroControl Corp.
8333 Rockside Road
Valley View, OH 44125-6104

Dear Ms. Richardson:

We are writing to you because during an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on November 20-22, 2000 and February 5-15, 2001, our Investigators collected information that revealed serious regulatory problems involving the NeuroControl Freehand System which is manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device. The law requires that manufacturers of medical devices conform with the requirements of the Quality System Regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that the device is 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, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System Regulation as follows:

Failure to establish and maintain adequate corrective and preventive action procedures. Not all sources of quality data are analyzed to identify existing and potential causes of nonconforming product and other quality problems. For example, only information gathered from your complaint system that pertains to the external control unit (ECU), the implantable receiver stimulator (IRS) and the transmit coil (TC) are analyzed in order to capture quality problems that may have occurred after your devices are distributed. Other failures/problems noted in the complaint system such as unintentional stimulation, infections, poor grasp function and battery charger failures are not evaluated/analyzed and processed through your firm's corrective and preventive action system. There is no rationale why other events are not trended and analyzed.

Furthermore, on October 10, 2000 your firm initiated an IRS recall where poor grasp function was the symptom of the device failure. The FDA inspection revealed that there were eight complaints reported due to poor grasp function, which is one of the "other" failures/problems in your firm's complaint system that are not trended/analyzed to capture quality problem.

Failure to establish and maintain an adequate complaint handling program. Complaints received by your firm are not processed in accordance with your firm's SOP in that there was missing information on the complaint form e.g., if the event involved a patient injury (block D) and MDR analysis (block H). In addition, complaints are not evaluated in a timely manner to determine if the reported events should be reported under the Medical Device Reporting (MDR) regulation.

We received your letters dated March 7, 2001 and March 31, 2001 in response to a Form FDA 483 dated February 15, 2001 that was issued to management at your firm. Your response was not adequate to correct all of the violative conditions at your firm. As explained in this letter, your Corrective and Preventive Action Procedures and Complaint Handling Procedures do not appear to be adequate. We note that your firm has developed a new procedure for "Field Report Handling" and Field Reports are now listed as inputs for corrective and preventive action in your firm's new "Corrective and Preventive Action" procedure. However, it was not clear from your response if all information gathered from these reports would be trended or analyzed so that your firm can take appropriate corrective and preventive action.

Also, in your firm's response to the FDA 483, you stated that your firm consistently files MDR reports within 30 days of becoming aware that an event is reportable. FDA generally considers that a manufacturer becomes aware of an adverse event whenever an employee becomes aware of an adverse event. The 30-day time frame begins the day after receipt of the information that reasonably suggests that a MDR reportable event has occurred.

In a meeting with your firm on April 18, 2000 in regard to an incident where returned recovered product from the field was inadvertently returned to approved inventory, we discussed your firm's handling of the return of the excess electrodes in the electrode kits that are supplied to surgeons by your firm. In that meeting you stated that your firm was looking for ways to improve the process. According to the FDA Investigator, your firm still has the policy of having the surgeon return the remaining unused electrodes to NuroControl or the surgeon on consignment maintains the unused electrodes. There is still a question of how long a surgeon keeps these extra electrodes on consignment before they would need to be reprocessed e.g., resterilized.

Also, at the time of the meeting your firm was using a procedure entitled, "Return Inspection Procedure for the Freehand Backup Implantable Components". As we stated in our meeting with your firm, this procedure appears to involve electronic record. The recent FDA inspection revealed that your firm is also utilizing electronic record keeping (a new Field Reports Database) in your CAPA procedure. In your March 31, 2001 letter of response to the FDA 483 it was indicated that the Field Reports Database is currently being validated and is scheduled for full implementation by April 16, 2001. However, your response did not outline your firm's global action plan to address all record keeping issues at your firm.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the FDA inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the 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 drugs and devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject device have been corrected.

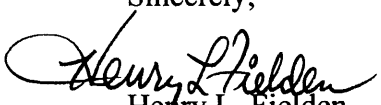
In order to facilitate FDA in making the determination that Quality System Regulation corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts and to resume export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that he/she has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the medical device Quality System Regulation (21 CFR, Part 820).

You should also submit a copy of the consultant's report, and certification by your firm's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant. The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates: October 5, 2001, October 5, 2002, and October 5, 2003.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Road, Cincinnati, Ohio 45237.

Sincerely,



Henry L. Fielden
District Director
Cincinnati District

Enclosure