DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
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FEB 2 2 2000

FDA

February 14, 2000

Dr. Matthew Israel, President
Judge Rotenberg Center
240 Turnpike St.
Canton, MA 02021-2341

Dear Dr. Israel:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your premises from January 31 – February 1, 3 & 10, 2000 at 240 Turnpike St., Canton, MA by the U. S. Food and Drug Administration (FDA).

This report is being provided to you for information purposes. This new procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it reflects redactions made by the Agency in accordance with the FOIA and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and, possibly, obtaining any information under FOIA.

If you have any questions, please feel free to contact Domenic Veneziano, Food and Drug Administration, One Montvale Ave., Stoneham, MA 02180, at (781)279-1675 ext. 144.

Sincerely,

Gail T. Costello
Acting District Director
New England District Office

Enclosure
FMD00-065

Judge Rotenberg Center
240 Turnpike St
Canton, MA. 02021-2341
CFN: 1222743 FEI: 1000120805

1/31/99 2/1, 3 & 10/00
LMD

Reason for Inspection

This inspection of the Judge Rotenberg Center in Canton, MA. was conducted as the result of consumer complaint number NEW-2042, attathment #1. The complaint alleges that the Graduated Electronic Decelerator (GED) and GED 4 are not reliable for use. It also alleges that when the devices are reported as malfunctioning, they are not properly tested and are sent back to be used again. The inspection was conducted in accordance with CP 82845B, Inspection of Medical Devices and 81010 Medical Device Reporting. It is FACTS assignment #66008.

History of Business

The Judge Rotenberg Center, formerly known as Behavioral Research Institute (BRI) is located in Canton, Massachusetts. The facility was previously located in Providence, Rhode Island. The Judge Rotenberg Center (JRC) continues to operate day and residential programming tracks for children and adults with behavior problems, including conduct disorders, emotional problems, head injuries, autism and developmental disabilities, (see exhibits #1-3 for center literature). There are one hundred and two students enrolled in the program. Dr. Matthew Israel remains the President and Executive Director of the firm.

Summary of Findings

On January 31, 2000 I visited the Judge Rotenberg Center located at 240 Turnpike St., Canton, MA. Credentials were displayed and an FDA 482 notice of inspection was issued to Ms. Ann Marie Iasimone (see attachment #2). Ms. Iasimone stated that she is the Assistant Director and the most responsible person of the firm at the time of my visit. It was explained that Dr. Matthew Israel who is the President and Director of the firm was in a meeting and would not be available. Dr. Israel was not present throughout the inspection. Ms. Iasimone introduced me to Mr. Robert Duquette, Assistant to Director for Human Resources. Mr. Duquette was present for the entire inspection.

Also present during the inspection were Mr. Jerry Kutcher, Electronics Consultant, Mr. Mike Corrigan, Electronics Consultant and Mr. George J. Wallace, the firm's attorney. These three individuals provided the majority of information contained in this report.

The center uses devices that deliver electro shocks to patients as part of the overall behavior modification program. There are currently three types of devices being utilized by the center on approximately 35 students. Those devices are the GED1, GED3a and the GED4. These units are manufactured at the center and are used exclusively by the center. The center currently has one approved 510(k) for the GED1, K911820. It was explained that the GED3a is an enhancement of the GED1. There are currently ten GED3a devices manufactured to date. The GED3a is being used on four students.

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The GED4 is another device that was manufactured and first utilized in 1992. Dr.Von hyne is a clinical psychologist who supervises the overall program for students in his caseload. He stated that there are six students currently using the GED4 device. He believes that there were approximately forty units manufactured to date. He explained that the differences between the GED and the GED4 are that the GED4 output is 45 RMS while the GED output is 15 RMS. Also the GED 4 utilizes two 12V batteries. The GED4 is currently being used on six students. No specific submissions with respect to the GED3a or the GED 4 have been made.

It was explained that each patient is a ward of the court and has a court appointed guardian, a court appointed monitor who is a psychologist, a court appointed neurologist and a court appointed attorney. Both the court and the Massachusetts Department of Mental Retardation are aware of and have approved the treatment plans provided for each student.

After discussions with NEW-DO compliance branch and CDRH, it was determined that the firm is exempt form 510(k) notices, and the device is considered to be within the practice of medicine. (See attachment #3).

I was instructed to close the inspection and not to issue an FDA 483.

When I returned to the firm, on 2/10/00 Dr. Matthew Israel was present for the close out via telephone, as well as George Wallace the firm's attorney. Also present were Robert Duquette, Director of Human Resources, Ann-Marie Iasimone, Assistant Director, Jerry Kutcher, Consultant and Glenda Crookes, Director of Residents and Student Services. I explained that it was determined that the firm was exempt under 807.65(d), and I would not be issuing an FDA 483. However, deficiencies were discussed throughout the inspection and the firm asked if I would go over those deficiencies with them. I agreed to do so and relayed the following to them: Deficiencies found at the firm included; lack of device history records, incomplete device master records, incomplete failure investigations and the lack calibration schedules for devices that are to be calibrated every 90 days.

I thanked Dr. Israel and his employees for their time, and the inspection was closed. The firm promised to work on the deficiencies noted above.

Attachments

#1 Complaint NEW-2042
#2 FDA 482 Notice of Inspection
#3 E-mail from Compliance RE: JRC

Exhibits

#1 - #3 Judge Rotenberg Center Literature

Lynne M Dwyer

Lynne M. Dwyer
NEW-DO Inspector