DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

09/07/2016

PAUL E PETERSON

5 Midland Road
Wellesley MA 02482 USA

In Reply refer to:
2016-7308
Requester Control #:

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

JUDGE ROTENBERG EDUCATIONAL CENTER INC - AVERSIVE THERAPY, AVERSIVE CONDITIONING DVCS, ELECTRICAL STIMULATION DVCS (ESD) UNTITLED LTRS 5/23/10, 6/29/12, WARNING LTR 12/7/12, 483 11/23/10, ETC

In partial response to your request, we are providing you with records that have previously been released under FOIA that are responsive to your request. Your request remains open with other agency components, and you will receive additional responses directly from those components. You will receive appeal rights with your final agency response.

The following charges for this request to date may be included in a monthly invoice:

Reproduction	Search	Review	Fiche	Other	Total
$1.20	$26.50	$0.00	$0.00	$0.00	$27.70

All communications regarding this request should be addressed to: Division of Freedom of Information, 5630 Fishers Lane, Room 1035, Rockville, MD 20857. Telephone: 301-796-3900. Email FDAFOIA@fda.hhs.gov.

Sincerely Yours,

SARAH KOTLER
Director

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

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 587-7500
FAX: (781) 587-7556

NWE-05-11

VIA UPS Next Day Air

May 23, 2011

Dr. Matthew Israel
Executive Director
The Judge Rotenberg Educational Center.
240 Turnpike Street
Canton, MA 02021 -2359

Dear Dr. Israel:

During an inspection of your firm located in Canton, MA on November 9, 2010, through November 23, 2010, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures Graduated Electronic Decelerators (GED) devices, models GED3A and GED4. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

A review of our records indicates that we cleared a premarket notification (510(k)), K911820, for a GED device on December 5, 1994, with the following indication: "GED is indicated for the treatment of patients, usually diagnosed as retarded or autistic, who exhibit self-injurious behavior of sufficient intensity and frequency to cause serious damage to themselves. The device should be used only on patients where alternate forms of therapy have been attempted and failed."

In 2000, our office told you that the Judge Rotenberg Center and its GED devices were exempt from the 510(k) requirement pursuant to 21 CFR 807.65(d). We have learned that this is not accurate. While licensed practitioners are exempt from this requirement in certain circumstances, the exemptions at 21 U.S.C. 360(g) and 21 CFR 807.65 only apply to classes of *persons*, and do not exempt the *device* from applicable clearance and approval requirements. Since the devices that you manufacture are not within a type that is 510(k)-exempt, see 21 U.S.C. 360(*l*) and (m), they are subject to FDA clearance and approval requirements.

This inspection revealed that your organization has significantly changed or modified the GED device since obtaining clearance. The following constitute significant changes or modifications that require a premarket notification:

(1) As described on the device label for the GED3A and GED4, you have modified the intended use of the device by adding "severe behavior problems" to the indications. The term "severe behavior problems" signifies a new patient population that is not included in the cleared indications and that raises new questions of safety and effectiveness since it is not clear that this type of behavior would respond similarly to this intervention.

(2) The GED4 has a significantly higher device output than the cleared device. Specifically, our investigator obtained from your firm, "Safety Assessment of the GED Device," which indicates that current output (b) (4) load. Another document obtained from your firm, "Memo to File, Re. GED 3A and GED-4", indicates that the GED4 output (b) (4) load. The current output of the GED4 raises concerns of tissue heating and burns, and requires clinical data to validate the safety and effectiveness of this change.

(3) The "Safety Assessment of the GED Device" indicates that you have introduced two automated features to the GED3A and GED4 that were not part of the cleared device: (a) an automated stimulus when the patient removes either hand from their hip-holsters, and (b) a seat board that initiates a stimulus if the patient stands from their chair. These automated features could significantly affect the safety or effectiveness of the device and requires clinical data to evaluate.

These constitute significant changes or modifications that require a new premarket notification under 21 CFR 807.81(a)(3). As a result, the GED3A and GED4 devices are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

Our inspection also revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g).

For example, when management representatives for your firm were asked if a validation plan had been created for the GED4 device, the representatives stated that it had not been created. Design Validation for the GED4 was not completed.

2. Failure to establish and maintain adequate procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria and failure to document acceptance activities required by this part, as required by 21 CFR 820.80(d) and (e). For example,

   a. When management representatives for your firm were asked for the quality acceptance test specifications, final testing instructions, repair or test procedures, calibration procedures, and final acceptance criteria for the GED4 device, the representatives stated that these documents did not exist. Acceptance limits for the GED4 device are not specified in the Device History Record (DHR).

   b. Section 3.0 of the GED3A Test Procedure, ELEC-WI 013 REV C, dated 11/18/99, requires that the therapy voltage remain between (b) (4) of 13 DHRs for the GED3A lists the voltage as approximately equal to (b) (4) Additionally, GED3A unit #(b) (4) was released on 7/5/06. The test data associated with the DHR for this device, however, is dated 9/28/06, 2½ months after final release.

3. Failure to establish and maintain a Design History File (DHF) for each type of device that contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part, as required by 21 CFR 820.30(j).

   For example, the DHF for the GED4 device was not available at the time of the inspection. When management representatives for your firm were asked for the DHF, the representatives stated that it did not exist.

4. Failure to designate an individual(s) to review for adequacy and approve prior to issuance of all documents established to meet the requirements of this part, as required by 21 CFR 820.40(a).

   For example, the GED3A Test Procedure, ELEC-WI 013 REV C, dated 11/18/99, which defines the procedure your firm shall use for the testing of the GED3A system, has not been signed and is, therefore, an uncontrolled document. Additionally, MFGINST-001, Rev. 7.0 Manufacturing Instructions for GED3A; ELEC-WI 005 REV 3, dated 8/8/00, Manufacturing for GED-3A; ELEC-0011 REV F, dated 3/03/10, GED Calibration; ELEC-0013 REV A, dated 2/24/97, Procedure for Medical Device Reporting; and ELEC-WI 0010 REV A, dated 6/4/99, Verification and Validation Plan are unsigned as well.

5. Failure to maintain adequate device master records (DMRs), as required by 21 CFR 820.181.

For example, the DMR for the GED3A device does not identify the Manufacturing Instructions, MFGINST-001, Rev 7.0. Additionally, the DMR for the GED4 device does not identify the manufacturing procedures, test procedures, or quality assurance procedures and acceptance criteria for the device.

We received your response dated December 3, 2010, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. Your response is not adequate because:

1. You did not provide evidence of implementation of design verification and design validation procedures for the GED4.

2. You did not provide documentation of evidence that you reviewed all DHRs for each lot of the GED3A and GED4 devices to ensure that the acceptance criteria were met and that the devices should have been released according to your procedure.

3. You did not provide documentation of design reviews of the GED4 as part of the DHF to ensure the DHF for the GED4 is complete.

4. You did not provide evidence of implementation of a DMR for the GED4 device.

Our inspection also revealed that your GED3A and GED4 devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation. Significant violations include, but are not limited to, the following:

Failure to adequately develop, maintain, and implement written MDR procedures for internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, as required by 21 CFR Part 803.17(a)(1).

For example, your procedure includes numerous outdated references that demonstrates your procedure has not been updated as necessary to comply with current regulations. These outdated references do not ensure timely and effective communication of events that may be subject to MDR requirements.

You did not address this in your response dated December 3, 2010.

If you wish to discuss any concerns related to 21 CFR 803, you may contact the MDR Policy Branch, formerly the Reporting Systems Monitoring Branch, at 301-796-6670 or by email at RSMB@fda.hhs.gov.

Please notify this office in writing within thirty (30) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violation(s), or similar violation(s), from occurring again. Include documentation of the corrections and/or corrective actions you have taken. If

your planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of these activities. If corrections and/or corrective actions cannot be completed within 30 working days, state the reason for the delay and the time within which these activities will be completed.

Your response should be sent to: Karen Archdeacon, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180. If you have any questions about the content of this letter please contact: Karen Archdeacon at (781) 587-7491.

In addition, we have scheduled a meeting at New England District Office on July 13, 2011 to discuss this letter and your proposed corrections and/or corrective actions. Please notify Ms. Archdeacon at the above number to confirm this date or to reschedule a mutually convenient time.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violation(s) at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violation(s) noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violation(s), and take prompt actions to correct the violation(s) and to bring your products into compliance.

Sincerely yours,

for Mutahar S. Shamsi
District Director
New England District

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

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 587-7500
FAX: (781) 587-7556

June 29, 2012

Glenda Crookes
Interim Executive Director
The Judge Rotenberg Educational Center
240 Turnpike Street
Canton, Massachusetts 02021-2359

Dear Ms. Crookes:

On November 9, 2010, through November 23, 2010, the U.S. Food and Drug Administration (FDA) inspected your manufacturing facility located at 240 Turnpike Street, Canton, MA. As a result of this inspection, we sent a letter to your firm dated May 23, 2011 indicating your GED3A and GED4 devices are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). Our letter also described serious problems with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (21 CFR), Part 820 and the Medical Device Reporting regulation found at 21 CFR Part 803. On July 13, 2011, a Regulatory Meeting was held at our office to discuss these deficiencies. During this meeting, we discussed the need for your firm to come into compliance as soon as possible.

We are in receipt of eleven (11) responses that were in response to our May 23, 2011 letter. These were dated July 21, 2011, September 14, 2011, October 14, 2011, November 15, 2011, December 15, 2011, January 20, 2012, February 24, 2012, March 20, 2012, April 17, 2012, May 11, 2012 and June 15, 2012. The FDA has completed our evaluation of your firm's corrections and corrective actions and provide our responses below.

Premarket Notification:

Our May 23, 2011 letter indicated that your organization has significantly changed or modified the Graduated Electronic Decelerators (GED) devices since obtaining initial FDA clearance on December 5, 1994 (K911820). We have reviewed your firm's responses to our letter and conclude that they are not adequate. (b) (4)

(b) (4)

In your responses, dated July 21, 2011 and September 14, 2011, your firm requested enforcement discretion which would allow the continued use of the GED3 and GED4 devices until a new 510(k) has cleared. We have reviewed your response dated July 21, 2011, and determined that your responses are not adequate. Your firm has not provided: 1) sufficient evidence to support the safety and effectiveness of these devices for treating aggressive behavior; 2) sufficient documentation to adequately characterize the output of the GED4 device and to determine the stimulation received by a patient; and 3) any information regarding the physical and/or psychological consequences of a student being placed in a pseudo restraint via the holster. Based on the inadequacy of the documentation provided in your responses, we disagree that enforcement discretion should be applied in this circumstance.

Your responses have indicated that a 510(k) notice for the GED3A and GED4 devices and its accessories was being prepared (b) (4)

GMP's

We have reviewed all of your responses that addressed the GMP observations noted in our May 23, 2011 letter. We acknowledge that your firm has hired (b) (4) as a third party design, development and manufacturing firm and that they will be manufacturing these devices for your facility in the near future. We note that your responses have not yet addressed the following items.

- Your firm has not provided design validation procedures to demonstrate the device conforms to defined user needs or its intended use.
- Your firm has not provided evidence of how the final release specifications for the GED3 or GED4 were determined or how the specifications relate to the final acceptance criteria for these devices.
- Your firm has not provided acceptance criteria for the GED devices in your DHR (QMS-007).
- Your firm has not provided a list of specific design input requirements in your Design Control Program (Document No. QMS-015). You have provided a general listing of design input requirements but does not list any specific design input requirements.
- Your firm has not provided: 1) a listing of all of the documents that encompass its QMS; 2) documentation regarding the review of the QMS for implementation of the Document Control (QMS-003); and 3) documentation indicating that all uncontrolled or obsolete quality system documents are no longer in use.
- Your firm has not provided a Device Master Record.

Please keep in mind that during a reinspection of your facility, we will need to verify that you are in compliance with all applicable regulations.

MDR's

Your responses were reviewed by FDA's Office of Surveillance and Biometrics (OSB). Upon review of your September 14, 2011 response, we acknowledge that your firm revised its MDR procedure to remove outdated references. However, your firm also removed information from its original procedure that should have remained in place. As such, the document now fails to meet the requirements of 21 CFR 803.17. The revised MDR procedure titled Medical Device Reporting, Doc: REG-001, Rev. A, effective: 09/12/11 does not meet the requirements of 21 CFR 803.17.

The following issues were noted in the revised MDR procedure:

1. REG-001, does not describe an internal system that provides for a standardized review process or procedure for determining when an event meets the criteria for reporting under this part. For example, there are no instructions for conducting a complete investigation of each event and evaluating the cause of the event.

2. REG-001, does not describe an internal process that provide for timely transmission of complete medical device reports to FDA. For example, there are no instructions for how to obtain and complete the FDA Form 3500A. The address identifying where MDR reports should be submitted is not included in the procedure. The address for MDR submission is: FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002.

In addition, Attachment 1 titled "Medical Device Reporting Decision Tree" is not readable as the print is very small. It is recommended that your firm revise Attachment 1 to make it readable for the user.

Additionally, the adequacy of your response dated November 15, 2011, cannot be determined at this time. The information provided in Attachment 14 included a spreadsheet with limited information for the complaints received. Your firm stated that it received a complaint referencing a second degree burn for which "first aid was applied." Your firm determined that the event was not reportable. Without additional information from clarifying what type of "first aid was applied" to the patient, it cannot be determined whether the application of first aid to a second degree burn represents medical intervention necessary to preclude permanent impairment of a body function or permanent damage to a body structure and therefore cannot at this time determine if your assessment of reportability is correct.

If your firm wishes to submit MDR reports via electronic submission it can follow the directions stated at the following URL:

http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm

If your firm wishes to discuss MDR reportability criteria or to schedule further communications, it may contact the MDR Policy Branch at 301-796-6670 or by email at MDRPolicy@fda.hhs.gov.

Please be advised that it is your firm's responsibility to assure compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority.

We request that you provide us with an additional written response within 30 business days from the date you receive this letter.

Your firm's additional response should be sent to: Karen Archdeacon, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180. If you have any questions about the content of this letter, please contact: Karen Archdeacon at (781) 587-7491.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,

Mutahar S. Shamsi
Director
New England District

Cc: (b)(4)
Robert Duquette, Judge Rotenberg Educational Center

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 587-7500 Fax:(781) 587-7556 Industry Information: www.fda.gov/oc/industry	10/03/2012 - 10/17/2012* FEI NUMBER 1000120805

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Glenda P. Crookes, Executive Director

FIRM NAME	STREET ADDRESS
The Judge Rotenberg Educational Center, Inc.	250 Turnpike St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Canton, MA 02021-2359	Medical Device

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for design validation have not been adequately established.

Specifically, your quality manager stated that the designs of your graduated electronic decelerator (GED) devices models GED3A and GED4 have not been validated. No design validation report was available in the design history file for these models. Data is not available to demonstrate that the devices meet user needs and intended uses.

OBSERVATION 2

The design history file does not demonstrate that the design was developed following the requirements of 21 CFR 820.

Specifically, the design history files for the GED3A and GED4 are incomplete. For example, the design inputs document provided for both models entitled (b) (4) [redacted], is in draft form and does not reference the GED4.

OBSERVATION 3

Premarket clearance or approval was not obtained prior to implementing significant changes to a medical device.

Specifically, on 5/23/11 your firm was notified by FDA that your Graduated Electronic Decelerator (GED) devices models GED3A and GED4 have not been approved or cleared by FDA. Your firm continues to maintain the GED3A and GED4

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Maura Rooney, Investigator	10/17/2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 587-7500 Fax:(781) 587-7556 Industry Information: www.fda.gov/oc/industry	10/03/2012 - 10/17/2012* FEI NUMBER 1000120805

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Glenda P. Crookes, Executive Director

FIRM NAME	STREET ADDRESS
The Judge Rotenberg Educational Center, Inc.	250 Turnpike St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Canton, MA 02021-2359	Medical Device

devices and use them on clients for aversive behavioral therapy. On October 3, 2012 you provided a report from your GED tracking database showing (b)(4) clients were wearing a total of (b)(4) GED3A devices and (b)(4) clients were wearing a total of (b)(4) GED4 devices. The labels of your GED3A and GED4 devices continue to state that the device is intended for "severe behavior problems", and the GED4 continues to be operated at a significantly higher outpu(b)(4)) than the cleared device.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Maura Rooney, Investigator MRooney	10/17/2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 587-7500 Fax:(781) 587-7556 Industry Information: www.fda.gov/oc/industry	10/03/2012 - 10/17/2012* FEI NUMBER 1000120805

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Glenda P. Crookes, Executive Director

FIRM NAME	STREET ADDRESS
The Judge Rotenberg Educational Center, Inc.	250 Turnpike St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Canton, MA 02021-2359	Medical Device

Observation Annotations

Observations intentionally left blank.

* DATES OF INSPECTION:
10/03/2012(Wed), 10/04/2012(Thu), 10/10/2012(Wed), 10/17/2012(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Maura Rooney, Investigator	10/17/2012

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

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 587-7500
FAX: (781) 587-7556

WARNING LETTER
CMS # 367480

VIA UPS Next Day Air

December 6, 2012

Glenda Crookes
Executive Director
The Judge Rotenberg Educational Center
240 Turnpike Street
Canton, Massachusetts 02021-2359

Dear Ms. Crookes:

On October 3, 2012, through October 17, 2012, an investigator from the United States Food and Drug Administration (FDA) inspected your facility located at 250 Turnpike Street, Canton, Massachusetts. As a result of this inspection, we observed the Graduated Electronic Decelerators (GED) 3A and GED4 devices at your facility. Our inspection revealed that your firm has an inventory of (b) (4) GED3A devices and (b)(4) GED4 devices, for a total of (b) (4) GED devices. Furthermore, our inspection revealed that use of the GED devices has been authorized for (b) (4) students through the Massachusetts Probate Court.

In a letter dated May 23, 2011, FDA notified your facility that the changes and modifications to the originally-cleared GED device require a new premarket notification under 21 CFR 807.81(a)(3). As a result, the GED3A and GED4 devices violate the Federal Food, Drug, and Cosmetic Act (Act) because your facility has failed to obtain FDA clearance or approval. Specifically, the devices are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your facility does not have an approved application for premarket approval in effect, pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g).

In a letter dated June 29, 2012, FDA again notified your facility that the GED3A and GED4 devices are adulterated and require the submission of a premarket notification. In responses to the letters dated May 23, 2011, and June 29, 2012, your facility stated that it is planning to make a submission under section 510(k) of the Act, 21 U.S.C. § 360(k), for changes and modifications to the GED3A and GED4 devices by December 2012. We still have not received any submission from your facility.

Your facility should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your facility's response to this letter should be sent to: Karen Archdeacon, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180. If you have any questions about the content of this letter, please contact Ms. Archdeacon at (781) 587-7491.

In addition, we have scheduled a meeting at the FDA campus in Silver Spring, Maryland, Building 66 on Wednesday, January 9, 2013, to discuss the contents of this letter and to discuss your proposed 510(k) submission. The purpose of this meeting will be to discuss an appropriate transition period, as of the date of the meeting, to discontinue use of the violative GED3A and GED4 devices. Use of violative devices after this transition period may subject those devices and responsible persons at your facility to enforcement action, including product seizure, without further notice. Please contact Ms. Archdeacon, at the above number to confirm this date or to reschedule a mutually convenient time.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your facility's responsibility to ensure compliance with applicable laws and regulations administered by FDA.

Your facility should investigate and determine the causes of the violations noted in this letter, in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the close of the inspection, and in the letters dated May 23, 2011, and June 29, 2012.

Sincerely yours,

Mutahar S. Shamsi
District Director
New England District

JUDGE ROTENBERG CENTER

A behavioral school for children and adults...

December 21, 2012

Karen Archdeacon
Compliance Officer
Food and Drug Administration
One Montvale Ave, 4th Floor
Stoneham, MA 02180

BY ELECTRONIC AND OVERNIGHT MAIL

Dear Ms. Archdeacon:

The Judge Rotenberg Educational Center, Inc. ("JRC" or "the Center") is hereby submitting this letter to the U.S. Food and Drug Administration's ("FDA" or "the agency") New England District in response to the Warning Letter received by the Center on December 7, 2012. The Warning Letter was issued to the Center following an inspection of JRC's facility located in Canton, MA from October 3 through October 17, 2012. It was explained to JRC by the investigator that the purpose of this inspection was to follow up on the corrective actions provided by JRC in the Center's various responses and correspondences to FDA Untitled Letters issued on June 29, 2012 and May 23, 2011. A Form FDA 483 also was issued to the Center following the inspection on October 17, 2012. JRC submitted a response to the Form 483 on November 6, 2012. In that response, JRC identified the various corrective actions that had been completed to date, as well as those actions that were underway to address FDA's inspectional observations. Though most of the items identified in the Form 483 are not addressed in the agency's December 7, 2012, Warning Letter, JRC assures the agency that significant progress continues to be made on the Center's comprehensive Corrective Action Plan.

JRC takes very seriously the issues raised in the Warning Letter and looks forward to meeting with FDA, as the agency requested, on January 9, 2013. At that meeting, JRC will reiterate the information provided in this letter including, among other things, the Center's strategy and timeline for submission of a new 510(k) notice for the Graduated Electronic Decelerator ("GED") devices. JRC also will be prepared to discuss an appropriate transition period to discontinue use of the Center's GED devices, versions GED3A and GED4, following clearance of the forthcoming 510(k). JRC also intends to discuss the physical and emotional harm that would be caused by any further FDA action that would require the removal, or transition from treatment, of the GED to other therapies which have previously been determined to be not effective for these clients. As noted in this response, any action by the agency that would remove or require the removal of the GED from the clients who currently rely on this therapy would have dire consequences from a client safety and health perspective.

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As the focus of the agency's Warning Letter pertains to the regulatory status of the GED – particularly the GED3A and GED4 - the remainder of this response will focus on the Center's efforts to prepare and submit a new 510(k) to obtain clearance for modified versions of the GED. In addition, since the Center has been apprising FDA in writing on a monthly basis of its efforts in this regard, the majority of the information contained in this response has been provided to the agency in prior correspondence. Nonetheless, the information is being provided again to serve as the Center's response to the December 7, 2012 Warning Letter.

Background on JRC

By way of background, JRC is an educational center that provides treatment and educational services to disabled children and adults with severe behavior disorders and other disabilities such as developmental disabilities and emotional disorders. For severe cases in which no other treatment is effective, the Center may, after obtaining approval from a Court of competent jurisdiction, add aversive therapy (*i.e.*, negative consequences) to the existing positive behavioral treatment plan for a particular, named client. Such aversive therapy administered with the GED devices is added only in accordance with a specific court order for the treatment of that client, and in compliance with state law and regulations. In addition, as discussed in detail below, numerous other controls are put into place to ensure the safe use of the device.

Treatment with the GED is intended to be used in conjunction with positive reinforcement behavior therapies and in response to harmful behaviors, including violent aggression, head-banging, physical attacks on others, property destruction, disruptive behavior, and self-mutilation, among others. The device is worn by the client for whom its use has been ordered by the court. When activated, the GED provides a low grade, but assertive electric shock to the surface of the client's skin. Specifically, the device sends a two second electric shock to an electrode attached to the surface of the client's skin on the inner/outer forearm, upper arm, upper thigh, calf, torso/stomach, palms of hands, soles of feet, or upper/outer quadrant of the buttocks. Clients may wear one or more (up to five) of these electrodes, but receive only one application at a time. It is most common for a client to wear one GED.

Regulatory and Compliance Background

JRC received clearance of a premarket notification ("510(k) notice") for the first GED model on December 5, 1994 (K911820). Since that time, JRC has enhanced the GED device with additional safety features and currently uses two versions of the device: the GED3A and the GED4. The GED3A model, (b) (4) (voltage) output, is configured for use with either a concentric electrode or a distanced (or spread) electrode. The GED 4 model, which provides (b) (4) – (b) (4) output, uses only a distanced electrode.

Following an FDA inspection in 2000, JRC was advised by the agency that a Form FDA 483 would not be issued because the GED devices were not subject to FDA's 510(k) requirements. Specifically, FDA stated that:

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

The foregoing written statement from FDA is provided in **Attachment #1**.

Although JRC has enhanced the original GED to the currently used GED3A and the GED4 models, as a result of FDA's statement in 2000, JRC reasonably believed that the GED3A and GED4 devices were exempt from premarket notification requirements. It was not until JRC received a May 23,

2011, Untitled Letter that the Center became aware of FDA's change in position with respect to the regulatory status of the GED3A and GED4.

Even though the GED is only used within the Center, and JRC does not commercially market, sell, or distribute the GED, to date, JRC has not challenged FDA's change in jurisdictional position. Rather, JRC has worked cooperatively with the agency by promptly developing and implementing a comprehensive corrective action plan intended to bring the center into compliance with FDA requirements and expectations in light of the agency's change in regulatory position. For example, among other things, JRC met with representatives of the New England District office on July 13, 2011, to discuss the Center's plans to address FDA's concerns. Also, on June 17, 2011, JRC retained and has continuously worked with an expert third party Quality Systems consultant, (b) (4) (b)(4), as well as JRC's regulatory counsel, (b) (4) "), to revise or establish over 30 standard operating procedures and forms. (b) (4) to (b) (4) . JRC's comprehensive corrective action plan has been provided to the agency on several occasions, including the original version on September 14, 2011 and in the Center's various monthly updates and status reports.

With respect to a 510(k) for the GED, JRC promptly initiated efforts to prepare a new 510(k) notice to address the devices after receipt of FDA's May 23, 2011, Untitled Letter. However, JRC acknowledges that it has not been able to submit this 510(k) notice in the timeframe that the Center had initially identified. Though significant progress has been made, JRC believes that it has a reasonable basis to justify these delays. In particular, while efforts to prepare the 510(k) notice were well underway, the Center determined that it would be more efficient and practical to outsource design activities to a competent and recognized third party. The possible outsourcing of the design and manufacture of the devices was in fact encouraged by FDA at the Center's meeting with FDA on July 13, 2011, in light of the fact that JRC is primarily an educational institution and not a medical device manufacturer. Accordingly, JRC retained the services of (b) (4) ") (b) (4) . (b) (4) (b) (4) (b) (4) . These modifications are intended to ensure compliance with currently recognized consensus standards and to ensure that the devices are designed in full compliance with FDA's design control requirements, sufficiently documented and properly verified and validated to demonstrate that the devices perform as intended and meet defined user needs.

Accordingly, the delay in the submission of the 510(k) notice is the result of retaining a qualified third party and developing redesigned GED devices – hereinafter referred to as the GED3B and GED4B.

(b) (4)

Ongoing Controls In Place – Current Use of the GED

While JRC and (b) (4) work together to design and verify the GED3B and GED4B devices, the Center continues to utilize the existing devices for the treatment of clients at the Center. The continued use of these products is imperative in the treatment of the (b)(4) clients who are currently utilizing the existing systems. The ongoing use of the GED is monitored by numerous special controls. Specifically, before the GED can be used in the treatment of a client, the following steps, among others, are required to take place:

a) Other therapies used to treat the client have failed;
b) The parent/guardian must provide written informed consent;

c) A Ph.D.-level licensed psychologist or a Ph.D.-level Board Certified Behavior Analyst must prepare an appropriate treatment plan;
d) A peer review committee must review the plan and deem it appropriate;
e) The school district or agency that referred the client to JRC also must approve the treatment plan and incorporate it into the client's Individualized Education or Service Plan;
f) A physician must certify the absence of medical contraindications to the use of GED3A or GED4;
g) A human rights committee must approve the treatment plan; and
h) The client must be assigned by a Massachusetts Probate and Family Court his or her own court-appointed independent counsel who may hire court-funded experts, as appropriate, to evaluate the client and oppose the treatment in court, if warranted, and the treatment plan must be authorized by a Massachusetts Probate and Family Court.

In addition, each use of the GED is administered under the direction of Ph.D.-level licensed psychologists or Ph.D.-level Board Certified Behavior Analysts. Further, each such use of the GED device is documented and, per JRC protocol, each client is evaluated by a nurse within 24 hours of the treatment being administered.

Continued use of the GED3A and GED4 does not raise any significant safety issues. In this regard, the parameters of the GED 3A and GED 4 have remained consistent over the past 20 years and has produced no harm as demonstrated by a review of approved testing/calibration procedures (ELEC-0010, ELEC-0011, QMS-019), and forms (Form 0010.1, 0011.1, and QMS-019.1) from February 2000 to October 2012. This belief is further supported by a review of quarterly reports provided to a Court Appointed Monitor as directed by the MA Bristol County Probate Court which grants JRC approval for GED treatment. This review showed that from September 1995 through August 2012, (b)(4) GED applications were given without any adverse effects. In addition, there are hundreds of findings by the Massachusetts Probate and Family Court that the GED 3A and GED 4 have not caused clients any adverse side effects.

JRC firmly believes that these controls are sufficient to continue to ensure the safety of the clients being treated with the device, and that the benefits of the continued treatment with the device far outweigh its risks. Due to the unprecedented treatment benefits of the GED, these clients are currently free from the severe pain and bodily injury caused by their violent self-abuse and they are receiving an education, living skills training, and a quality of life that was not possible for them before treatment with the GED. Documentation of their treatment and education progress, including hundreds of Massachusetts Probate and Family Court findings, is available at JRC. Further, no adverse events have been observed which were attributed to the device.

Safety Risks Associated with Removal of, or Transition from, the GED

Considering the severity of the disabilities of each specific client who is currently utilizing the device, terminating use of the GED, or removing these devices from the Center, would likely cause the clients to suffer irreparable harm including permanent disfigurement or death due to the likely reoccurrence of the violent and self-mutilating behaviors that are currently being successfully treated with the GED device. The dangerous behaviors in which these clients are frequently engaged prior to their treatment with the GED device included head banging, eye gouging, tearing their own flesh, biting off body parts, pulling out their own adult teeth, destroying furniture and school equipment, punching their fists through glass windows, running into traffic, jumping out of windows, and violently attacking family members, teachers, staff and others with punches, kicks, bites and sharp objects such as razor blades and eating utensils. Descriptions of these life-threatening and severely painful behaviors, along with descriptions of all of the treatments that were tried and failed to successfully treat the behaviors, including massive dosages of medication, are documented in the treatment records from the many facilities at which these clients were treated prior to their placement at JRC.

These clients were treated with all available forms of treatment at psychiatric hospitals and many other types of residential treatment programs prior to their placement at JRC and these facilities could not effectively treat the behaviors or keep the client safe. A sampling of these prior treatment records is provided in **Attachment 2.**

Attachment 3 provides a letter from a consulting physician, (b) (4), regarding the potential consequences that would result from the removal of the GED from a client's treatment plan. (b) (4) *curriculum vitae* is also provided in **Attachment 3.**

As noted by (b) (4) without use of the GED, alternatives for these clients to control the undesirable and often dangerous behaviors would likely be limited to (1) a regimen of psychotropic drugs or (2) physical, mechanical, and chemical restraints. Medication and/or restraint will not treat the clients' behavior disorders and will not allow them to be educated and develop skills. Rather, such treatment protocols will simply sedate the client and cause very harmful side effects.

Use of Psychotropic Drugs

Therapy with a cocktail of psychotropic medications would render the clients in a semi-comatose state where they would be sedated, incommunicative and requiring constant care for daily life activities including feeding. It was the effect or failure of these drugs and other treatment regimens which led physicians and parents to refer these clients to JRC in the first place, and for treating clinicians at JRC to elect to use the GED devices in the treatment of these clients. The side effects of antipsychotic medications, can include, for example, major weight gain,[1] severe sedation, acute and chronic extrapyramidal syndromes (e.g. tardive dyskinesia, akathisia, dystonia, parkinsonism),[2] neuroleptic malignant syndrome,[3] sexual dysfunction,[4] prolactin elevation,[5] sudden cardiac death,[6] nocturnal enuresis,[7] addiction, increased likelihood of diabetes, and/or life-shortening metabolic

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[1] Allison, D.B., Mentore, J.L., Moonseong, H., Chandler, L.P., Capelleri, J.C., Infanted, M.C. and Weiden, P.J. (1999). Antipsychotic-induced weight gain: A comprehensive research synthesis. *America Journal of Psychiatry, 156 (11),* 1689-1696.

Correll, C.U., Manu, P., Olshanskiy, V., Napolitano, B., Kane, J.M., & Malhotra, A.K. (2009). Cardiometabolic Risk of Second-Generation Antipsychotic Medications During First-Time Use in Children and Adolescents. *Journal of the American Medical Association, 302(16),* 1765-1773.

[2] Tarsy, D., Lungu, C., & Baldessarini, R.J. (2011). Epidemiology of tardive dyskinesia before and during the era of modern antipsychotic drugs. In Weiner and Tolosa (Eds.), *Handbook of Clinical Neurology: Hyperkinetic Movement Disorders. Volume 100. (pp. 601-616).* Edinburgh: Elsevier.

Marder, S.R., & van Kammen, D.P. (2005). Dopamine receptor antagonists (typical antipsychotics). In B.J. Saddock & V.A. Saddock (Eds.), *Comprehensive Textbook of Psychiatry* (pp. 2817-2838). Philadelphia, PA: Lippincott Williams & Wilkins.

[3] Adnet, P., Lestavel, P., and Krivosic-Horber, R. (2000). Neuroleptic malignant syndrome. *British Journal of Anaesthesia, 85(1),* 129-35.

[4] Serreti, A., & Chiesa, A. (2011). A meta-analysis of sexual dysfunction in psychiatric patients taking antipsychotics. *International Clinical Psychopharmacology, 26 (3), 130-140.*

[5] Rosenbloom, A.L. (2010). Hyperprlactinemia with antipsychotic drugs in children and adolescents. *International Journal of Pediatric Endocrinology, 2010,* 1-6. doi: 10.1155/2010/159402

[6] Ray, W.A., Chung, C.P., Murray, K.T., Hall, K., & Stein, M.B. (2009). Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death. *The New England Journal of Medicine, 360,* 225-235.

[7] Harrison-Woolrych, M., Skegg, K., Ashton, J., Herbison, P., & Skegg, D.C.G. (2011). Nocturnal enuresis in patients taking clozapine, risperidone, olanzapine and quetiapine: comparative cohort study. *British Journal of Psychiatry, 199,* 140-144. doi: 10.1192/bjp.bp.110.087478

changes.[8] Moreover, the side effects related to the use of drug therapies are severe as opposed to the side effects associated with the use of the GED which are minimal or non-existent. As detailed in an article recently submitted for publication comparing the risk-benefit analysis of antipsychotic medication and contingent skin shock for the treatment of destructive behaviors by Nathan A. Blenkush, Director of Research at JRC (**Attachment 4**), the side effects of antipsychotic medications are more numerous and severe than those associated with Contingent Skin Shock.

Use of Physical Restraints

The other possible alternative to the GED or drug regimen is the use of physical restraints. However, use of such treatment could have serious psychological effects and has led to death in other facilities. For example, data tracked by the Coalition Against Institutionalized Child Abuse indicates that between 1988 and 2006 there were 75 deaths resulting from physical restraint (*see* http://www.caica.org/RESTRAINTS%20Death%20List.htm, last accessed December 18, 2012.)

Use of the GED

In contrast to these other therapies, the GED devices allow clients to learn productive behaviors to replace their dangerous behaviors, perform daily life tasks and interact with others, allowing for their continued education and training development and therapy. The GED devices does not have the same harmful side effects as drugs or restraints.

Any action by the agency that would precipitously remove or require the eventual removal of the GED from the clients who currently rely on this court-ordered therapy would have dire consequences from a client safety and health perspective. To this end, the client's behavioral disabilities, and the pain and physical and emotional harm to the client caused by them, have also been described on numerous occasions by the parents of these clients, and by the clients themselves, at court hearings, legislative hearings, and to the media. The parents and clients have also described all of the other treatments that were tried and were not successful in stopping the dangerous behaviors. They have described the unprecedented and formerly impossible educational progress their children have been able to accomplish at JRC once their dangerous and disruptive behaviors were successfully treated with the GED device. Just a small sampling of the letters that these parents have written to legislators and other government officials explaining the critical need for access to the GED device are attached hereto as **Attachment 5**.

A public and graphic illustration of these clients' dire need for the GED device occurred at a public legislative hearing in Massachusetts on July 26, 2011 concerning a bill to ban aversive treatment, including the GED device, which ultimately failed to pass. At the hearing, a family member had the GED device removed from the child immediately before standing to address the committee with the child next to him. As he spoke to the committee members about how the GED treatment had saved the child's life, he had to struggle to hold the child to prevent him from hitting and slapping himself in the face. These behaviors resurfaced only minutes after the GED device was removed from the client's body.

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[8] For a history and evaluation of the use of psychotropic drugs with individuals with intellectual disabilities, see Levitas, A. S. & Hurley, A. D. (2006a). The history behind the use of anti-psychotic medications in persons with intellectual disability: Part I. *Mental Health Aspects of Developmental disabilities, 9,* (26-32). http://www.judgerc.org/LevitasAntipsycholtc.pdf and Levitas, A. S. & Hurley, A. D. (2006b). The history behind the use of anti-psychotic medications in persons with intellectual disability: Part II. *Mental Health Aspects of Developmental disabilities, 9,* (93-98). Both articles as well as a third article by the same authors in 2008 are available at http://www.judgerc.org/LevitasAntipsycholtc.pdf. For an article by William Carpenter, M.D. that points out that antipsychotic drugs can take years off of a person's life, see Carpenter, W., (2007). Choosing the right antipsychotic. *The Carlat Psychiatry Report, Vol. 5, No. 3,* 4-5 (also available at http://www.judgerc.org/CarpenterArticle.pdf).

According to Massachusetts State Regulation (115 C.M.R. § 5.14 et seq.), and a January 7, 1987, consent decree signed by the Commonwealth of Massachusetts and approved as an Order of a Massachusetts Court, aversive interventions, such as the GED device, may be used in Massachusetts when approved by a Massachusetts Probate and Family Court after a hearing. The client is represented by a court-appointed attorney and the client's counsel is given the opportunity to review the treatment plan and oppose it with the assistance of a court-funded expert witness. *See The Judge Rotenberg Educ. Center, Inc. v. Comm'r of the Dep't of Mental Retardation* (No. 1), 424 Mass 430, 443-445 (1997). The critical need, and lack of alternatives, for this treatment is also the subject of hundreds of judicial findings where Massachusetts Probate Courts decided to approve or renew court approval of the use of the GED device at JRC with a client after conducting the hearing and reviewing evidence of: the client's diagnosis; past unsuccessful treatments; the client's severe behavior disorder; and the success of the GED device effectively treating the behaviors with no adverse side effects. A sampling of the most recent Court Findings and Orders concluding that the treatment is safe, effective and causes no side effects, for the eighty-four clients at JRC currently receiving GED treatment, is provided as **Attachment 6**.

The GED device is the only treatment available to these clients to keep them safe, healthy, and allow them to achieve academic progress and independence. Removing these clients' access to the GED device could return them to their self-destructive behaviors, seclusion and constant physical, mechanical and chemical restraint, as the only means to attempt to stop them from killing or maiming themselves. Removal also will likely end the significant educational and behavioral progress they have made at JRC and this loss of progress could be permanent and is considered irreparable harm by law. The prior treatment records and judicial findings concerning these clients prove conclusively that the massive dosages of medication, restraint and other intrusive interventions used with them prior to their treatment with the GED device, failed to stop them from causing severe pain and physical damage to themselves, and, in many cases, caused them to suffer painful and permanent side-effects such as the devastating side-effects of anti-psychotic medication identified above. The prior treatment records also demonstrate that drugs and restraint will not stop these clients from engaging in their dangerous behaviors so they will still cause severe pain and harm to themselves in addition to receiving these ineffective and intrusive alternative treatments.

The GED treatment causes a rapid deceleration of these clients' dangerous and disruptive behaviors down to zero or near-zero levels and on average the client receives less than two (two second) GED applications per week. JRC's educational program teaches these clients to replace their problematic behaviors with positive behaviors such as social, recreational, and educational activities. There is no doubt that the loss of this highly effective and safe treatment will cause devastating and permanent harm to these clients. These clients have rights to receive effective treatment, and to be free from harmful, ineffective treatments, under Federal Statute and the Constitution of the United States. *See* 20 U.S.C. § 1400, et seq.; 29 U.S.C. § 794; U.S. Const. Amend. XIV.

In light of the safety and efficacy information presented above, along with the demonstrated need to for the device in treating this limited group of clients, the Center believes that any seizure action, or mandated transition period to remove clients from the GED would cause significant adverse health effects on the clients. Any such transition plan should be limited to a transition from the GED-3A and GED4 to the GED3B and GED4B, respectively. The Center will be prepared to discuss this issue at the forthcoming meeting with FDA on January 9, 2013.

* * *

We look forward to meeting with the agency on January 9, 2013. Prior to that meeting, should you require any further information or have questions, please do not hesitate to contact me at (781) 828-2202.

Sincerely,

Glenda P. Crookes
Executive Director

Attachments

cc: Robert Duquette, Judge Rotenberg Educational Center
(b) (4)
(b) (4)