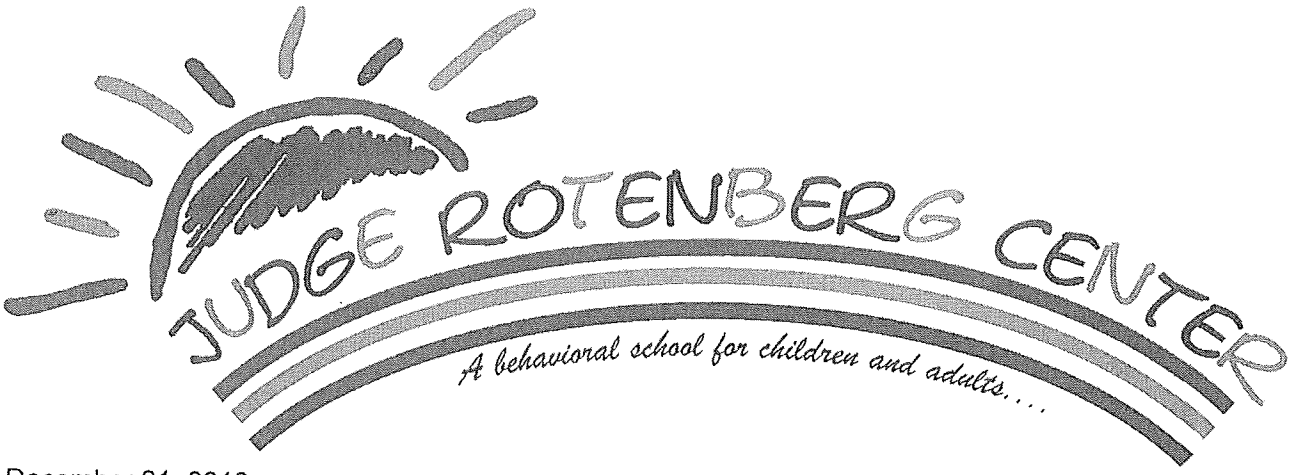

December 21, 2012

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.

250 Turnpike Street, Canton, MA 02021-2341 • Tel (781) 828-2202 • Fax (781) 828-2804 • www.judgerc.org

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

---

[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.

---

[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/LevitasAntipsychoitc.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/LevitasAntipsychoitc.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)
[redacted]