Text-accessible version. *Transcribed by Lydia Brown, www.autistichoya.com, 4 April 2013.*

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

OFFICE OF P-12 EDUCATION: Office of Special Education
ASSISTANT COMMISSIONER
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[seal of the University of the State of New York]

March 12, 2013

Ms. Glenda Crookes
Executive Director
Judge Rotenberg Educational Center
240 Turnpike Street
Canton, MA 02021-2359

Dear Ms. Crookes:

Upon review of the "Warning Letter" CMS #367480 issued by the Department of Health and Human Services, Food and Drug Administration (FDA) on December 6, 2012 to the Judge Rotenberg Educational Center (JRC), and your responses thereto, the New York State Education Department (NYSED) finds JRC in violation of 8 NYCRR §200.22(f)(2)(viii) which states:

> *The use of any aversive conditioning device used to administer an electrical shock or other noxious stimuli to a student to modify undesirable behavioral characteristics shall be limited to devices tested for safety and efficacy and approved for such use by the United States Food and Drug Administration where such approval is required by Federal regulation.*

In the above-referenced warning letter, the FDA states:

> *"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."*

Therefore, consistent with the March 5, 2013 order by the Honorable Gary L. Sharpe, Chief Judge of the U.S. District Court, Northern Distrit of New York, NYSED requires JRC to cease use of the GED-3A and GED-4 devices with NYS students with disabilities not later than 30 days of receipt of this letter. All parties affected by this corrective action have been notified. This notification, which provides 30 days' notice to JRC, replaces the corrective action letter issued to you on January 15, 2013.

As noted on the FDA website "Premarket Approval (PMA) is the most stringent type of device marketing application required by FDA. A PMA is an application submitted to FDA to request approval to market. Unlike premarket notification, PMA approval is to be based on a determination by FDA that the PMA **contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses**." (emphasis added) 8NYCRR §200.22(f)(2)(viii) specifically requires that devices used for aversive interventions be "limited to devices tested for safety and efficacy and approved for such use by the FDA where such approval is required by federal regulation." Without premarket approval, the devices have not been 'tested' and determined to be safe and effective for their intended use or uses. The use of the word "approval" for purposes of the above-referenced regulation was intended to encompass all requirements by FDA regarding such devices, including premarket approvals.

JRC was first notified by the FDA that the above-referenced devices did not have FDA clearance or approval as early as May 2011, yet you chose not to disclose this information to the New York State Educational Department (NYSED), despite your direct knowledge since 2006 of New York State (NYS) regulations that specifically require FDA approval or clearance of devices used for aversive conditioning. It is JRC's responsibility to ensure compliance with applicable NYS laws and regulations relating to the education of NYS' students with disabilities.

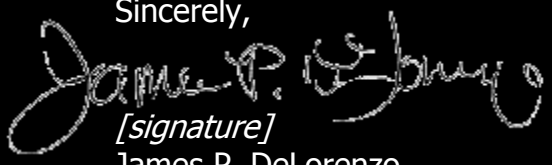
In a letter dated January 18, 2013, Mr. Flammia raises the claim that "treatment with the GED devices is federally mandated by the students' IEPs." While the IEPs of the NYS students may indicate use of Level III aversives or a GED device, only one specifies the use of the GED 4 device. Further, while IDEA guarantees a free appropriate public education (FAPE), 34 CFR §300.18 specifically states that FAPE means special education and related services that meet the standards of the State Educational Agency. The standards of this State include the requirement for a prohibition on the use of aversive interventions, except as provided in 8 NYCRR §200.22(e) and that the use of any aversive conditioning device used to administer an electrical shock or other noxious stimuli to a student to modify undesirable behavioral characteristics shall be limited to devices tested for safety and efficacy and approved for use by the FDA. The FDA has publicly posted that the GED3A and 4 do not meet their standards for a determination that they are "safe and effective for its intended use or uses."

Nothing in Mr. Flammia's response to the New York State Education Department (NYSED) provides any documentation that the FDA now finds these devices safe for use, even during a transition period. Further, Mr. Flammia states "JRC is currently assessing the time that it would take to revert back to use of the original version of the GED device" … and that the "time it will take to revert back to the original version of the GED device is being reviewed and is unknown at this time." Even if a transition period were appropriate, it would be irresponsible and inappropriate for NYSED to authorize JRC to continue to use devices not tested and determined to be safe with NYS students. As I stated in my letter of January 15, 2013 if you have a letter or other documentation indicating that the FDA finds it safe to continue the use of such devices during a transition period or that it has issued premarket approval of such devices, determining them to be "safe and effective for its intended use or uses," then you should immediately fax that information to me.

In Mr. Flammia's January 18, 2013 letter, he notifies NYSED that JRC no longer manufactures the FDA-approved GED devices or has devices in your inventory. (This is information that was not previously disclosed by JRC to NYSED.) Therefore, you must take immediate steps to provide an authorized device to implement the students' IEPs or, until such time as the FDA notifies JRC that such devices have been determined safe for continued use, you must implement an interim alternative behavioral intervention plan with these students that does not include the use of GED 3A or GED 4. We are notifying each of the school districts that their Committees on Special Education must take immediate action to address this issue in the students' IEPs.

In summary, effective 30 days from receipt of this letter, unless otherwise directed by the court, JRC must cease the use of the GED 3A and GED 4 devices with NYS students until such time as the FDA notifies you that the use of such devices have the required FDA approvals. If you have additional information from the FDA that it has determined that it is safe to use such devices during a transition period, and you would like to discuss this transition plan, please contact my office to arrange a meeting.

Sincerely,



[signature]
James P. DeLorenzo

c: Hon. Gary L. Sharpe
Kelly L. Munkwitz, Esq.
Michael Flammia, Esq.
Jeffrey J. Sherrin, Esq.
Meredith H. Savitt, Esq.