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March 6, 2017

VIA FEDERAL EXPRESS

Ms. Claire B. Stansbury
Information Technician
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

RE: Freedom of Information Act Request Reference No. 2017-1440 – Request for Expedited Processing

Dear Ms. Stansbury:

On December 27, 2016, I submitted a letter to the U.S. Food and Drug Administration's ("FDA") Chief Counsel, Ms. Dickinson. The letter requested certain documents. I received a February 15, 2017 letter from the FDA acknowledging receipt of my letter and informing me that the FDA is treating my letter as a Freedom of Information Act ("FOIA") request (the "FOIA Request") and has assigned you as my point of contact in connection with the same.

I write to you now to request expedited processing of the FOIA Request. Under FOIA, agencies must expedite processing whenever it is demonstrated that there is a "compelling need", which includes circumstances where failure to obtain the records on an expedited basis "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual" or at the agency's discretion. 5 U.S.C.A. § 552(a)(6)(E)(v)(I); Id. at § 552(a)(6)(E)(i)(II); 21 C.F.R. § 20.44(a)(l).

The following information supports my request for expedited processing and I certify that it is true and correct to the best of my knowledge and belief. The FDA has proposed banning electrical stimulation devices ("ESDs") used to treat self-injurious behavior ("SIB") or aggressive behavior ("AB") (the "Proposed Ban"). *See* 81 Fed. Reg. 24386. I am an authorized representative of the Judge Rotenberg Educational Center, Inc. ("JRC"), a health care facility directly responsible for treating patients who engage in severe and life-threatening SIB and AB (e.g., head banging, eye gouging, tearing their own flesh, biting off body parts, pulling out their own adult teeth, punching their fists through glass windows, running into traffic, jumping out of windows, swallowing knives and violently attacking family members, teachers, staff and others with punches, kicks, bites and sharp objects). ESDs have proven to be the only effective treatment for these dangerous behaviors for these individuals, all of whom

have been unsuccessfully treated with other therapies. These patients are currently receiving treatment with ESDs at JRC and ESD treatment is preventing them from engaging in severe SIB and AB that would otherwise threaten their health and put them at risk death and disfigurement.

The implementation of a ban would threaten the lives and physical safety of the JRC patients receiving ESD treatment. Now that the comment period has closed, the FDA could issue a Federal Register notice announcing a ban at any time. The patients and their family would receive no prior notice that the FDA has imposed a ban that would deprive the JRC patients of the one treatment that suppresses their dangerous SIB and AB, thereby putting them at risk of serious physical harm, including death. Many of the findings in the Proposed Ban about the safety and effectiveness of ESDs are false, as explained in detail in a comment JRC submitted to the FDA on July 25, 2016. *See* FDA-2016-N-1111-1637. JRC needs the FDA's documents that purportedly provide the underlying support for its findings, which I requested in my December 27, 2016 letter, so that JRC will have the information for any needed judicial action and so JRC can further attempt to demonstrate to the FDA that the FDA's findings about ESDs are inaccurate and based on false information. These document requests seek documents directly relevant to the FDA's key findings.

This is a case warranting expedited processing. The FDA's usual processing time of months (or sometimes years) would entirely frustrate the purpose of the FOIA Request because the FDA could issue a Federal Register notice announcing final agency action before JRC has received the requested documents. Receiving the documents after a ban goes into effect would be too late to protect the patients from the dangers that they would face immediately after the ban, before judicial relief can be sought.

I look forward to receiving notice of your determination as to whether expedited processing will be provided within the next 10 days, as required by 5 U.S.C.A. § 552(a)(6)(E)(ii)(I). I also look forward to receiving processed documents in an expedited manner.

If possible, I request the receipt of records as they become available instead of receiving a single response once all records asked for are available.

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Please notify me of all appeal procedures available under law.

Sincerely,

Michael P. Flammia, Esq.

cc: Elizabeth H. Dickinson, Esq., Chief Counsel (via electronic mail and federal express)
Glenda P. Crookes, Executive Director (via electronic mail)
Jeffrey N. Gibbs, Esq. (via electronic mail)