U.S. FOOD & DRUG ADMINISTRATION

May 5, 2023

Urotronic, Inc.
Attention: David Perry, CEO
2495 Xenium Lane N
Plymouth, MN 55441

Re: Submission of Clinical Trial Results Information Pursuant to 42 U.S.C. § 282(j)
FDA Reference Number: *GEN2300089*
NCT03423979

Dear Mr. Perry:

Based on an initial review of Food and Drug Administration (FDA) records, information from the ClinicalTrials.gov data bank operated by the National Library of Medicine, a part of the National Institutes of Health, and any available public information, it appears that your company is the "responsible party"[1] for the above-identified clinical trial, which appears to be an "applicable clinical trial"[2] subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11. We note that the Protocol Registration System (PRS) states that "[t]his study appears NOT to be an applicable clinical trial" based on the information entered when this study was registered; specifically, you entered that this trial was not studying an FDA-regulated device. This appears to be incorrect. As the *Final Rule, Clinical Trials Registration and Results Information Submission*, 81 Fed. Reg. 64,982, 65,013 (Sept. 21, 2016), explains:

> A clinical study of a device product that is being conducted entirely outside of the United States (i.e., does not have any sites in the United States or in any U.S. territory) and is not conducted under an [investigational device exemption] may not be a clinical study of a device product subject to section 510(k), 515, or 520(m) of the [Federal Food, Drug, and Cosmetic Act (FD&C Act)] and, therefore, is not an applicable device clinical trial, *depending on where the device product being used in the clinical study is manufactured. If the device product is manufactured in the United States . . . and is exported for study in another country . . . , the device product is considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act.*

Accordingly, this study appears to meet the definition of an "applicable clinical device trial" in 42 CFR 11.22(b)(1)(ii), because it is an interventional study; its primary purpose is other than a feasibility study; it studies a U.S. FDA-regulated device product; and it is manufactured in and exported from the U.S. for study in another country.

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[1] *See* section 402(j)(1)(A)(ix) of the Public Health Service Act (PHS Act) (42 U.S.C. § 282(j)(1)(A)(ix)) and 42 CFR 11.10 for the definition of "responsible party."

[2] *See* sections 402(j)(1)(A)(i) - (iii) of the PHS Act (42 U.S.C. § 282(j)(1)(A)(i) - (iii)) and 42 CFR 11.10 for the definition of "applicable clinical trial."

A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for the trial; such results information generally must be submitted no later than one year after the primary completion date[3] of the applicable clinical trial, unless the responsible party has submitted a timely certification of delay,[4] a request for an extension for good cause, or a request for a waiver of the requirements for submission of results information.[5]

FDA has identified potential noncompliance related to the above-identified clinical trial, titled "Evaluation of Optilume™ BPH Prostatic Drug Coated Balloon Dilation Catheter in the Treatment of Moderate-to-Severe Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia," a phase 2 interventional study to evaluate the device's use for the treatment of adult men with obstructive urinary symptoms associated with Benign Prostatic Hyperplasia (BPH). It appears that results information for the referenced applicable clinical trial has not been submitted to the ClinicalTrials.gov data bank. Your company should review your records of this clinical trial and determine whether your company submitted all required results information. If your company determines that results information is required and due for this clinical trial, please submit the results information promptly.

Failure to submit clinical trial information[6] required under section 402(j) of the PHS Act (42 U.S.C. § 282(j)), including information required under the regulations found in 42 CFR part 11, is a prohibited act under section 301(jj)(2) of the FD&C Act (21 U.S.C. § 331(jj)(2)). Beginning 30 calendar days after you receive this letter, FDA intends to further review and assess the above-identified clinical trial. If FDA determines that your company failed to submit any clinical trial information required under section 402(j) of the PHS Act (42 U.S.C. § 282(j)), including its implementing regulations in 42 CFR part 11, your company may receive from FDA a Notice of Noncompliance,[7] and FDA may thereafter initiate an administrative action seeking a civil monetary penalty.[8] In addition to civil monetary penalties, violations of section 301(jj) of

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[3] *See* 42 CFR 11.10 for the definition of "primary completion date." *See also* section 402(j)(1)(A)(v) of the PHS Act (42 U.S.C. § 282(j)(1)(A)(v)), which defines "completion date." As reflected in 42 CFR 11.10, the terms "primary completion date" and "completion date" are synonymous for the purposes of 42 CFR part 11.

[4] To be timely, the responsible party must submit a certification prior to the date of (i.e., the day before) the standard submission deadline for results information. *See* 42 CFR 11.44(b) and (c); *see also* https://clinicaltrials.gov/ct2/manage-recs/faq ("When is required clinical trial results information due?")

[5] *See* section 402(j)(3)(E) and (H) of the PHS Act (42 U.S.C. § 282(j)(3)(E) and (H)) and 42 CFR part 11, subpart C for results information submission requirements.

[6] *See* section 402(j)(1)(A)(iv) of the PHS Act (42 U.S.C. § 282(j)(1)(A)(iv)) and 42 CFR 11.10 for the definition of "clinical trial information."

[7] *See* section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. § 282(j)(5)(C)(ii)).

[8] Pursuant to section 303(f)(3)(A) of the FD&C Act (21 U.S.C. § 333(f)(3)(A)), "any person who violates section 301(jj) [of the FD&C Act (21 U.S.C. § 331(jj))] shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding." Moreover, section 303(f)(3)(B) of the FD&C Act (21 U.S.C. § 333(f)(3)(B)) provides that "[i]f a violation of section 301(jj) [of the FD&C Act (21 U.S.C. § 331(jj))] is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii) [of the PHS Act (42 U.S.C. § 282(j)(5)(C)(ii))], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected." These civil monetary penalty amounts reflect the amounts found in the statute. These amounts are updated annually to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. No. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. § 2461 note 2(a)), as amended by the

the FD&C Act (21 U.S.C. § 331(jj)) could result in other regulatory action, such as injunction and/or criminal prosecution, without further notice.

As requested, please review your company's clinical trial records, and submit any required results information to the ClinicalTrials.gov data bank. We also request that you review all applicable clinical trials for which your company is the responsible party to ensure compliance with all ClinicalTrials.gov registration and results information submission requirements. You can access the ClinicalTrials.gov website at https://register.clinicaltrials.gov/. If you have any questions about this letter, you may call Martin Hamilton, at 301-796-5666. Please have the FDA reference number provided at the top of this letter available when you call. Alternatively, you may e-mail FDA at martin.hamilton@fda.hhs.gov. Please include the FDA reference number with any email communications. As noted, it appears that you incorrectly identified this clinical trial in the ClinicalTrials.gov data bank as not studying an FDA-regulated device. Please update the record for this trial.[9]

We request that you submit a written response to FDA within 30 calendar days after you receive this letter, stating the actions that your company has taken in response to this letter. If you believe that your company has complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please send your response via email to Martin.Hamilton@fda.hhs.gov or bimo-cdrh@fda.hhs.gov and include the FDA reference number on all correspondence relating to this matter.

Sincerely,

Soma S. Kalb -S

Soma Kalb, Ph.D.
Director
DCEA1: Division of Clinical Policy and Quality
Office of Clinical Evidence & Analysis
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, November 2, 2015). For the most up-to-date amounts, please see 45 CFR 102.3.

[9] The FD&C Act also prohibits the submission of clinical trial information that is false or misleading in any particular. 21 U.S.C. § 331(jj)(3).