U.S. FOOD & DRUG ADMINISTRATION

VIA EMAIL

June 13, 2023

In My Bathroom (IMB)
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Re: FDA Reference Number: COR23000070

In My Bathroom (IMB):

This letter notifies you that the United States (US) Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) has determined that your business, as a manufacturer, has offered an electronic product, the Purple Glow Ultraviolet Sterilamp, model no. BP52 (hereafter "Ultraviolet Sterilamp", or "your product"), an Ultraviolet C (UVC) product, that has a defect under 21 CFR 1003.2(b)(2). This defect was identified on March 06, 2023, through a laboratory evaluation of a sample Ultraviolet Sterilamp.

Our determination that your product has a defect, which relates to the safety of use by reason of the emission of electronic product radiation, is based on the following:

1. The Ultraviolet Sterilamp is an electronic product whose primary purpose is as a handheld product intended to emit UV radiation for sanitization purposes. The Ultraviolet Sterilamp is intended to be held in the hand for the duration of the sanitization process, causing the user to be in close proximity to the source of the radiation for the entirety of the sanitization process. Through laboratory evaluation of the UV radiation emissions from your product, FDA measured the effective (actinic) weighted spectral irradiance in the 200 to 400 nm range as 2.2 W/m^2 (i.e., 0.22 mW/cm^2) at 5 cm from your product. The level of UV radiation emitted by your product presents a risk of injury to the user and nearby persons. The International Commission on Non-ionizing Radiation Protection recommends an exposure limit of 3.0 mJ/cm^2 effective spectrally weighted in the UV range, within an 8-hour period.[1] A person in the vicinity of the Ultraviolet Sterilamp, which would include a user, may receive an injury to their skin (e.g., erythema) and/or eyes (e.g., photokeratitis) from the Ultraviolet Sterilamp, in as little as 13.6 seconds (i.e., 3.0 mJ/cm^2 / 0.22 mW/cm^2) at a distance of 5 cm from the light

[1] International Commission on Non-ionizing Radiation Protection: Guidelines on Limits of Exposure to Ultraviolet Radiation of Wavelengths between 180 nm and 400 nm (Incoherent Optical Radiation). Health Physics 87(2):171-186, 2004.

source. In addition, our laboratory evaluation found that the sample Ultraviolet Sterilamp exceeded 1000 seconds actinic ultraviolet hazard (Es) Exposure Limit for Risk Group 2 according to subclause 6.1.3 of the Standard IEC 62471:2006 in 130 seconds (2.17 minutes) at a distance of 20 cm from your product. Therefore, your product was classified as a Risk Group 3 product (High Risk). As a result of its design, production or assembly, the Ultraviolet Sterilamp causes the user to be in close proximity to a radiation source without shielding and high level of UV radiation, and potentially exposes other persons in the vicinity to emitted radiation, and lacks features to mitigate such exposures, creating a risk of injury. These radiation emissions affecting the user and nearby persons are unnecessary to the accomplishment of the product's primary purpose of sanitizing objects and surfaces and create a risk of injury to persons.

2. According to the Ultraviolet Sterilamp's operating instructions, and our laboratory evaluation, the Ultraviolet Sterilamp has a built-in timer limiting the operation time to 180 seconds. Per the labeling, the Ultraviolet Sterilamp is intended to be held in the hand for the duration of the sanitization process. As a result of its design, production or assembly, the Ultraviolet Sterilamp causes the user to be in close proximity to a radiation source without shielding and high level of UV radiation, and potentially exposes other persons in the vicinity to emitted radiation creating a risk of injury to the skin and/or eyes of the user or nearby persons. This is true even if the Ultraviolet Sterilamp operation while being held in the hand is limited to the operation time set by the timer. Moreover, even if the timer goes off, the Ultraviolet Sterilamp can be turned on again by double clicking the on/off button. As discussed in item #1 above, the internationally accepted exposure limit is based on cumulative exposure over a period of 8 hours. Therefore, this safety feature does not eliminate the Ultraviolet Sterilamp's emission of electronic product radiation unnecessary to the accomplishment of its primary purpose, which creates a risk of injury to the user, and anyone nearby.

Due to the safety hazards presented by the Ultraviolet Sterilamp, and the lack of safety features, FDA has concluded, pursuant to 21 CFR 1003.2(b)(2), that the Ultraviolet Sterilamp has a defect that relates to the safety of use by reason of the emission of electronic product radiation because it is a product which utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended, and as a result of its design, production, or assembly, it emits electronic product radiation unnecessary to the accomplishment of its primary purpose, which creates a risk of injury to any person. FDA is thus providing notice under 21 CFR 1003.11(a) of FDA's determination that your product has a defect.

Because your product has a defect as defined under 21 CFR 1003.2, you are required, under 21 CFR 1003.11(b), to immediately provide a written response to FDA with the total number of referenced product units which have been produced and the approximate number of such product units that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas. You have 15 days after you receive this letter to respond in writing using one of the options listed below:

I. Refutation. Under 21 CFR 1003.11(a)(3), you may submit your views and evidence to establish that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of electronic product radiation.

II. Exemption Request. Under 21 CFR 1003.30(a), you may apply for an exemption from purchaser/subsequent transferee and dealer/distributor notification requirements in 21 CFR 1003.10(b). If exempted from such notification, you are not required to provide a repair, replacement, or refund for the defective products (under 21 CFR 1004.1(a)). Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31) and the information required under 21 CFR 1003.20.

III. Purchaser Notification and Corrective Action. If you neither refute the finding of defect nor request an exemption, then you must: (1) notify purchasers/subsequent transferees and dealers/distributors of the defective products as specified in 21 CFR 1003.10(b), and (2) submit a written corrective action plan (CAP) for approval showing how you will fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the defective products.

a. Notification Letter. Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and any subsequent transferees and dealers/distributors must also be sent to the FDA under 21 CFR 1003.22(a). It is recommended that you submit a draft of the notification letter(s) to us for review.

b. Corrective Action Plan. Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4. Such a plan must demonstrate how you will expeditiously correct the defect and fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the defective products and must be approved as set out in 21 CFR 1004.6.

Your firm should take prompt action (including, but not limited to, preparation of a CAP, completion of production changes, submission of required reports, etc.) to address any defects identified in this letter.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, we recommend you provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that the requirements to provide purchaser/subsequent transferee/dealer/distributor notification and the provision of copies of any such notification to FDA are separate from the requirements relating to CAP. If an acceptable CAP cannot be prepared promptly, you still may be required to proceed with notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. 360oo(a)) prohibits any person from failing to furnish notification, where required, or from failing to provide a repair, replacement, or refund of the cost of a product found to have a defect which relates to the safety of use of such product. Under Section 539(b)(1) of the Act, persons who violate section 538 of the Act may be subject to civil penalties of up to $3,198 per violation and up to a maximum penalty of $1,090,241

without further notification by FDA. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

Alternatively, you may request a regulatory hearing, which is an informal hearing under 21 CFR Part 16, regarding FDA's findings identified in this letter.[2] See 21 CFR 1003.11(a). If you choose to do so, your request, along with any supporting materials, should be received by FDA no later than 15 days from receipt of this letter, and should be sent to the CDRH Ombudsman Program at cdrhombudsman@fda.hhs.gov, and clearly entitled "Request for Part 16 Hearing." However, a request for a regulatory hearing is **not** required to respond to this letter with a refutation as described above. Submission of your views and evidence to refute the alleged defect as a written response, in accordance with option I above, is sufficient to assure your refutation will be evaluated.

This notice of opportunity for hearing will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest (21 CFR 16.22(d)).

Copies of the Federal Performance Standards, compliance guides, radiation safety product report guides, and other documents are available on FDA's web site at: http://www.fda.gov/Radiation-EmittingProducts/default.htm.

UVC lamp manufacturers are responsible for compliance with all applicable regulatory requirements. The applicable regulations include 21 CFR parts 1000 through 1004, and certain sections of 21 CFR part 1005, including 21 CFR 1005.25. These regulations include requirements that manufacturers of electronic products (such as UVC lamps) investigate and report Accidental Radiation Occurrences (21 CFR 1000.3(a) and 21 CFR 1002.20), issue notification to the FDA and customers of radiation safety defects and correction of those defects (21 CFR parts 1003 and 1004), and, for non-domestic manufacturers of UVC lamps, designate a U.S. agent (21 CFR 1005.25).

In addition to the information required above, you are requested to include the following information in your response to CDRH: (a) list all models of UVC products your firm manufactures (or imports, or has manufactured, or has imported) that have been, or are intended to be, imported into the United States; and (b) a description of each UVC product's intended use, safety features, intended emission spectrum and intended intensity.

Please email your response (in PDF format) to both RadHealthCustomerService@fda.hhs.gov and the identified FDA lead reviewer (identified in the closing paragraph) and including the subject Accession number or correspondence reference number.

Should you have any questions or comments pertaining to this letter, please contact Paul Lemaillet by e-mail at Paul.Lemaillet@fda.hhs.gov. In any follow-up correspondence, please clearly reference FDA reference number COR23000070 and include a contact email address.

[2] If the materials submitted do not show that there is a genuine and substantial issue of fact that warrants a hearing, the request for a hearing may be denied in whole or in part under 21 CFR 16.26(a). See also FDA's guidance document, "Center for Devices and Radiological Health Appeals Processes," March 2, 2022, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes.

Sincerely,

/S/

Robert Ochs, Ph.D.
Director
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health