U.S. FOOD & DRUG ADMINISTRATION

VIA EMAIL

June 17, 2021

Max-Lux Corporation, Ltd.
Longtoushan Industry Zone
Beiguan town, Yangdong District
Yangjiang City
529500 Guangdong
China

Max Lux Corp., Ltd.
03E-01-01, Yangxi Industry Zone
Yangxi
529800 Guangdong
China

kenny@max-lux.com
sales2@max-lux.com
sales06@max-lux.com

Re: FDA Reference Number: COR20000181; Opportunity for Hearing

Max-lux Corporation, Ltd., Most Responsible Officer:

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 "Safe•T•Lite" (also referred to as "OneTouch Safe T Lite, LLC" "Safe•T•Lite" and "Safe•T•Lite UV WAND") (hereafter "STL" or "your product"), an Ultraviolet C ("UVC") lamp, for import that has a defect under 21 CFR 1003.2(b)(2). This defect was identified on July 31, 2020, through a laboratory evaluation of a sample STL collected at John F. Kennedy International Airport on July 1, 2020. 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. STL is an electronic product whose primary purpose objectively is as a handheld product intended to emit UV radiation for sanitizing purposes. The STL instructions for use, which were provided by the destination agent but not included with the shipping package or with the multiple boxes containing an STL (hereinafter "STL unit box") inside the shipping package, instruct the user to "[h]old the UV-C lamp toward the items, leave 1 inch above surface and go back and forth slowly over the entire surface for 30 to 60 seconds to be sterilized." Following these directions would cause the user to hold the STL in the hand for the duration of the sterilization process, causing the hand to be in close proximity to the source of the radiation for the entirety of the sterilization 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 4.02 W/m^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 STL, which would include a user following the STL's instructions for use, may receive an injury to their skin (e.g., erythema) and/or eyes (e.g., photokeratitis) from the STL, in as little as 7.5 seconds. As a result of its design, production or assembly, the handheld STL 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. As discussed above, while a copy of the STL's instructions for use was provided by the destination agent and the STL's instructions for use did include warning statements – "[d]o not point the UV-C light toward eyes or skin as the light is harmful to your eyes and skin," and "[d]o not look direct at the UV-C light at any time. Could cause damage to your eyes" – the STL's instructions for use were not included with the shipping package or the STL unit box. Further, there were no labels on the STL itself, or on the STL's unit box, to indicate that UVC is emitted from the STL and that exposure to UVC may be hazardous. As a result, users would be directly exposed, without warning, to levels of UVC radiation that may be hazardous. As a result of its design, production, or assembly, including lack of labels on the product and lack of instructions for use, the STL exposes persons to a risk of injury from unnecessary emitted radiation (as discussed in item #1 above).

3. According to the STL instructions for use that were obtained from the destination agent, the STL has a "[s]afety [f]eature" that "[t]he UV-C light will only be on when facing downwards. If facing up the light will turn off." This safety feature does not eliminate the risk of injury to the user or anyone nearby from the unnecessary radiation discussed in item #1 above.

Due to the safety hazards presented by your product, and the lack of safety features, FDA has concluded, pursuant to 21 CFR 1003.2(b)(2), that the STL 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, including genetic 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.

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

[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.

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 request an exemption from the purchaser and any subsequent transferee and dealer/distributor notification requirements in 21 CFR 1003.10(b) (see item III). If exempted from such notification, you are not required to correct the violative products (as described in 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 defect nor request an exemption, then you must: (a) notify purchasers and any subsequent transferee (where known to the manufacturer or where the manufacturer, upon reasonable inquiry to dealers, distributors, or purchasers, can identify the present user) and dealers/distributors of the violative products, as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) for approval by FDA, as required by 21 CFR Part 1004, showing how you will fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative 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 dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

   b. Corrective Action Plan (CAP) - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, and/or 1004.4. Such a plan must expeditiously and effectively correct the defect and must be approved by FDA, as set out in 21 CFR 1004.6.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if you do not take action to address your product defect through one of the options listed above within 15 days, you may be required to proceed with notification to affected persons (see 21 CFR 1003.11(c)). Therefore, you are encouraged to immediately begin your preparation of accurate purchaser and dealer/distributor lists.

Additionally, you have the right to refute the findings in this letter by requesting a regulatory hearing before the FDA. However, a hearing is **not** required to respond to this letter with a refutation. Written submission of your views, along with evidence to refute the alleged defect, in accordance with option I above, is sufficient to assure your refutation will be evaluated. Information about requesting a regulatory hearing before FDA can be found in 21 CFR Part 16. A request for a regulatory hearing, as described in 21 CFR 16.22 and 1003.11(a)(3), must be received by FDA in writing within 15 days from receipt of this letter. Ensure that your request for a regulatory hearing is clearly marked "APPEAL." Please send all

materials related to a request for a regulatory hearing to the CDRH Ombudsman via email at CDRHOmbudsman@fda.hhs.gov.

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. FDA's eSubmitter may be used to prepare reports and correspondence, available at http://www.fda.gov/ForIndustry/FDAeSubmitter/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 lamp 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 lamp product's intended use, safety features, intended emission spectrum and intended intensity.

Please email your response to this defect notification (in PDF format) to RadHealthCustomerService@fda.hhs.gov, copying the FDA lead reviewer (identified in the closing paragraph) and including the subject correspondence reference number.

Should you have any questions or comments pertaining to this letter, please contact Pejman Ghassemi by telephone at +1-240-402-0313 or by e-mail at Pejman.Ghassemi@fda.hhs.gov. In any follow-up correspondence, please clearly reference FDA reference number COR20000181 and include a contact email address.

Sincerely,

Robert Ochs, Ph.D.
Deputy Director for Radiological Health
OHT 7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

CC: Richard Lapine
President
Cricket Product Labs
1075 Main Street, Fourth Floor
Waltham, MA 02451
[Main Lab]

Cricket Product Labs
Division Street, Unit 1-156,
Sag Harbor, NY 11963
[NY Product/Operations Lab]

Cricket Product Labs
Rm A06, 9F, No. 287 Nanjing East Road, Sec. 3, Songshan Dist.
Taipei, 05495
Taiwan, Republic of China
[Overseas Fulfillment Lab]

rick@thecricketlabs.com