December 22, 2020

Ms. Alexandra Dunn
Assistant Administrator, Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Mail Code: 7101M
Washington, DC 20460

Ms. Susan Bodine
Assistant Administrator, Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
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Washington, DC 20460

Dear Assistant Administrators Dunn and Bodine:

On behalf of the Light Source Section and Luminaire Section of the National Electrical Manufacturers Association (NEMA), I write seeking written guidance to confirm that manufacturers or importers of ultraviolet lights (UV lights) may identify such lights as "germicidal lights," may state on product literature and product packaging that UV light is "effective against most viruses, spores and cysts," and may make claims of a similar general nature involving bacteria, fungi, and other pathogens as supported by scientific research and consensus. NEMA has learned that EPA Region 4 has raised questions about whether such statements are consistent with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). NEMA seeks clarity from your offices that such descriptions do not violate FIFRA.

NEMA represents some 325 electrical equipment and medical imaging manufacturers that make safe, reliable, and efficient products and systems across 58 product Sections. Our combined industries account for 370,000 American jobs in more than 6,100 facilities covering every state. Our industry produces $124 billion in electrical equipment and medical imaging shipments per year, with $42 billion exported.

NEMA recognizes that the sale of lighting products that involve claims of preventing, destroying, repelling or mitigating any pest (including bacteria, viruses, and other pathogens) is subject to federal regulation by the EPA as a pesticide device under FIFRA. In addition to other applicable FIFRA requirements, pesticide devices may not be "misbranded," 7 U.S.C. §136j(a)(1)(F), which would include any "false or misleading"

statements about the lighting product, 7 U.S.C. §136(q)(1)(A). Examples of statements or representations that constitute misbranding include:

> (i) A false or misleading statement concerning the composition of the product;
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> (ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
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> (iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
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> (iv) A false or misleading comparison with other pesticides or devices;
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> (v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;
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> (vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;
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> (vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;
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> (viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;
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> (ix) Claims as to the safety of the pesticide or its ingredients, including statements such as “safe,” “nonpoisonous,” “noninjurious,” “harmless” or “nontoxic to humans and pets” with or without such a qualifying phrase as “when used as directed”; and
>
> (x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
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> > (A) “Contains all natural ingredients”;
> >
> > (B) “Among the least toxic chemicals known”
> >
> > (C) “Pollution approved”

40 C.F.R. §156.10(a)(5).

Identifying a product that produces UV light as a “germicidal light” and claiming that UV light is “effective against most viruses, spores and cysts” (and similar general claims involving bacteria, fungi, and other pathogens as supported by scientific research and consensus) is not misbranding under any of these categories. Specifically, it is not “a

false or misleading statement concerning the effectiveness of the product as a pesticide or device" under (ii) because the general effectiveness of UV light is firmly supported by peer-reviewed scientific studies.[1] The EPA itself has stated that UV light is effective at inactivating most viruses, spores and cysts,[2] and the U.S. Food and Drug Administration (FDA) has recognized the disinfecting quality of UV light.[3] Such statements are also not "used in such a way as to give a false or misleading impression to the purchaser" under (vii) because the claim does not identify any specific pathogens and does not assert any degree of efficacy.

In its 2020 Compliance Advisory titled "EPA Regulations About UV Lights that Claim to Kill or Be Effective Against Viruses and Bacteria," the EPA Office of Enforcement and Compliance Assurance made the following statement:

> Unlike chemical pesticides, EPA does not routinely review the safety or efficacy of UV light devices and, therefore, EPA has not conducted a human health risk assessment to determine the safety of these products. For the same reason, EPA cannot confirm whether, or under what circumstances, UV light devices might be effective against any pest, including viruses and bacteria. The effectiveness of any UV light device will depend on a variety of factors including, but not limited to, the device's duration of use, distance of the light from the surface intended to be treated, the UV wavelength, the specific pest being targeted, the strength or wattage of the UV light bulb, the age of the UV light bulb, shadow areas or other factors.

NEMA agrees that the extent to which UV light is effective against specific pathogens depends on these factors. A claim, therefore, that a particular UV light "kills 99.9% of SARS-CoV-2" would require specific substantiation. By contrast, a general claim that "UV light is effective against most viruses, spores and cysts," or a similar general claim supported by scientific consensus, would not constitute false or misleading labeling under FIFRA because that general statement is accurate and supported by decades of scientific studies and the EPA own statements.

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[1] https://www.iuvanews.com/stories/pdf/archives/180301_UVSensitivityReview_full.pdf; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2789813/

[2] https://www3.epa.gov/npdes/pubs/uv.pdf at 2 ("UV disinfection is effective at inactivating most viruses, spores, and cysts"); https://archive.epa.gov/nrmrl/archive-etv/web/pdf/p10012zq.pdf at 2, Table 2 (noting that advantages of UV disinfection include: "effective at inactivating most bacteria, viruses, spores and cysts").

[3] https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/uv-lights-and-lamps-ultraviolet-c-radiation-disinfection-and-coronavirus ("UVC radiation is a known disinfectant for air, water, and nonporous surfaces. UVC radiation has effectively been used for decades to reduce the spread of bacteria, such as tuberculosis.")

Identifying a UV light as “germicidal light” is also lawful and appropriate because it is a categorical identifier of a product as a UV light rather than as a light that provides general illumination. This industry-wide categorization is recognized and even required by the federal government. The FDA requires importers to identify the applicable product category for lights upon importation. The product category that applies to these lights is “UV lamp, germicidal.”[4] The inability for manufacturers to refer to UV lights as “germicidal lights” in product literature and product packaging would therefore be inconsistent with the FDA categorization of these lights.

Thank you for addressing this request for written guidance. If you have any additional questions, please feel welcome to contact me at peter.tolsdorf@nema.org.

Sincerely,

Peter Tolsdorf
General Counsel and Secretary

[4] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=RHP