UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

June 18, 2020

ELECTRONIC MAIL

Mr. Andrew McCarthy
President
Seal Shield, LLC
315 E. Robinson Street, Suite 500
Orlando, Florida 32801
andrew@sealshield.com

Re: Case No: FIFRA-04-2020-0703
Termination to Stop Sale, Use, or Removal Order

Dear Mr. McCarthy:

Enclosed is a termination to the Stop Sale, Use, or Removal Order (SSURO) (hereinafter "Termination") that the U.S. Environmental Protection Agency is issuing to Seal Shield, LLC (Seal Shield), pursuant to the authority set forth in Section 13 of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C.§ 136k. This Termination is effective immediately.

Pursuant to the Termination, the EPA is hereby terminating the remaining provisions of the SSURO that prohibit the sale, distribution, use and removal of the ElectroClave, UV Disinfectant/Device Manager (ElectroClave pesticide device), identified as a "misbranded pesticide device," in paragraph 46 (B) of the SSURO.

The EPA determined that it was appropriate to issue this Termination after reviewing Seal Shield's submitted data and the proposed efficacy claims for the ElectroClave device. Based on this data, Seal Shield's efficacy claims must be limited to:

- Claims for 99.9% reduction on hard non-porous surfaces with respect to the four pathogens: Staphylococcus, Escherichia coli, Methicillin-Resistant Staphylococcus Aureus and Carbapenem-Resistant Enterobacteriaceae for which data has been generated; and

- Each sale and distribution of the ElectroClave must be accompanied by a User Manual that identifies the need for mechanical removal of bio-burden and the importance of hand hygiene.

The EPA has also reviewed the labeling for the ElectroClave. As stated in EPA's email to Seal Shield on June 16, 2020, Seal Shield must revise the label to comply with the requirements in 40 CFR § 156.10.

The Termination is not a waiver by the EPA of any enforcement or other authority available to the EPA under FIFRA nor shall it act to release Seal Shield from any potential liability for violations of FIFRA that may have occurred prior to, or subsequent to the issuance of this Termination.

Please contact Marlene Tucker of the EPA Region 4 at (404) 562-9536 or via email at tucker.marlene@epa.gov if you have any questions or concerns regarding this Termination.

Sincerely,

CAROL KEMKER Digitally signed by CAROL KEMKER Date: 2020.06.18 17:31:11 -04'00'

Carol L. Kemker
Director
Enforcement and Compliance Assurance Division

Enclosure

cc: Neil Richmond, FDACS
Ed Schwartz, Attorney at Law, Sweetnam & Schwartz, LLC, ess@mseslegal.com