Message

From: Tucker, Marlene [Tucker.Marlene@epa.gov]
Sent: 7/20/2021 11:06:50 AM
To: Binford, Marshall [Binford.Marshall@epa.gov]
CC: Beard, Phillip [Beard.Phillip@epa.gov]; Caplan, Robert W. [Caplan.Robert@epa.gov]
Subject: FW: Status on the Termination of the Seal Shield FIFRA SSURO
Attachments: Declaration.6.18.20.pdf

Marshall,

As per your request, I am forwarding Seal Shield's certification of compliance signed on June 18, 2020.

Marlene Tucker

From: Ed Schwartz <ess@mseslegal.com>
Sent: Thursday, June 18, 2020 2:12 PM
To: Tucker, Marlene <Tucker.Marlene@epa.gov>; Andrew McCarthy <andrew@sealshield.com>
Cc: Beard, Phillip <Beard.Phillip@epa.gov>; Bingham, Kimberly <Bingham.Kimberly@epa.gov>; Hansen, Susan <Hansen.Susan@epa.gov>
Subject: RE: Status on the Termination of the Seal Shield FIFRA SSURO

Marlene,

Sorry for the confusion. As I stated during the previous call, the previous Declaration was intended to be comprehensive and apply not only to the products but also to the devices under the SSURO, as it clearly states that "SealShield is in compliance with the SSURO issued April 20, 2020 and FIFRA". Consequently, I was not under the impression that EPA was interested in another certification of this nature but a statement that the EPA requirements identified in the email for future sale of the ElectroClave would be implemented. I appreciate this clarification and have attached the requested declaration from Andrew McCarthy.

Please let me know if EPA has any other concerns.

Sincerely,

Ed Schwartz

"HONI SOIT QUI MAL Y PENSE"

SWEETNAM & SCHWARTZ LLC
1050 Crown Pointe Parkway, Suite 500
Atlanta, Georgia 30338
470-395-7842 (p)
678-360-3644 (m)
770-234-6779 (facsimile)

SWEETNAM & SCHWARTZ LLC

Confidentiality: This message and any attachments from Sweetnam & Schwartz LLC may contain confidential and legally protected information. If you are not the intended recipient (addressee) please do not read, copy, disseminate or disclose this communication. Please notify Sweetnam & Schwartz LLC by e-mail to ess@mseslegal.com if you have received this e mail in error and then securely delete from your system. No attorney/client relationship is formed with Sweetnam & Schwartz, LLC in the absence of a signed engagement letter. IRS Circular 230 Disclosure: To ensure compliance with requirements imposed by the IRS and other taxing authorities, any tax advice contained in this communication (including any attachments) is not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties that may be imposed on any taxpayer, or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

From: Tucker, Marlene <Tucker.Marlene@epa.gov>
Sent: Thursday, June 18, 2020 1:32 PM
To: Ed Schwartz <ess@mseslegal.com>; Andrew McCarthy <andrew@sealshield.com>
Cc: Beard, Phillip <Beard.Phillip@epa.gov>; Bingham, Kimberly <Bingham.Kimberly@epa.gov>; Hansen, Susan <Hansen.Susan@epa.gov>
Subject: RE: Status on the Termination of the Seal Shield FIFRA SSURO

Ed,

We are in receipt of your email. We appreciate Seal Shield's efforts to revise the User Manual for the ElectroClave. As per my recent discussions with you, Seal Shield will resubmit a certification of compliance from a company official authorized to sign the document stating the Seal Shield is in compliance with the terms of the SSURO applicable to the pesticide device (the ElectroClave) and the requirements of FIFRA. I am also attaching the previous certification of compliance that was submitted by Seal Shield for the Partial Termination of the SSURO which applied to the products that were categorized as "unregistered pesticide products," and not to the pesticide device.

With regards
Marlene Tucker

From: Ed Schwartz <ess@mseslegal.com>
Sent: Thursday, June 18, 2020 12:23 PM
To: Tucker, Marlene <Tucker.Marlene@epa.gov>; Andrew McCarthy <andrew@sealshield.com>
Cc: Beard, Phillip <Beard.Phillip@epa.gov>; Bingham, Kimberly <Bingham.Kimberly@epa.gov>; Hansen, Susan <Hansen.Susan@epa.gov>
Subject: RE: Status on the Termination of the Seal Shield FIFRA SSURO

Marlene,

Thank you for patience and for following up with me on this matter.

Per my phone call with Andrew McCarthy this morning, this is to certify compliance of SealShield with all of the requirements noted in your email dated June 16, 2020 regarding the ElectroClave device.

Regarding the User Manual, the following changes were made:

Additionally here is what was done:
1. The word safe was removed from: "ElectroClave provides a safe, secure and fully automated;"
2. The two statements, "ElectroClave can disinfect a non-porous, hard surface device achieving a 99.9% reduction of MRSA, S.aureus, E. coli, and CRE;" and "The ElectroClave will not penetrate inorganic and organic matter" were placed in the same paragraph in the "introduction" section and "cleaning and disinfection" section under "guidelines for use."

3. The "guidelines for use" section was moved to beginning of manual just after introduction
4. Specific examples of inorganic and organic matter were provided
5. Specific examples of non-critical medical devices were provided

Attached please find the updated User Manual with the changes in highlights. Further, SealShield will ensure that all of the revisions enumerated by EPA to the label will be made prior to sale or distribution of any ElectroClave device.

Please let me know if EPA requires any further information from SealShield.

Sincerely,

Ed Schwartz

"HONI SOIT QUI MAL Y PENSE"

SWEETNAM & SCHWARTZ LLC
1050 Crown Pointe Parkway, Suite 500
Atlanta, Georgia 30338
470-395-7842 (p)
678-360-3644 (m)
770-234-6779 (facsimile)

SWEETNAM & SCHWARTZ LLC

Confidentiality: This message and any attachments from Sweetnam & Schwartz LLC may contain confidential and legally protected information. If you are not the intended recipient (addressee) please do not read, copy, disseminate or disclose this communication. Please notify Sweetnam & Schwartz LLC by e-mail to ess@mseslegal.com if you have received this e mail in error and then securely delete from your system. No attorney/client relationship is formed with Sweetnam & Schwartz, LLC in the absence of a signed engagement letter. IRS Circular 230 Disclosure: To ensure compliance with requirements imposed by the IRS and other taxing authorities, any tax advice contained in this communication (including any attachments) is not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties that may be imposed on any taxpayer, or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

From: Tucker, Marlene <Tucker.Marlene@epa.gov>
Sent: Thursday, June 18, 2020 8:19 AM
To: Andrew McCarthy <andrew@sealshield.com>; Ed Schwartz <ess@mseslegal.com>
Cc: Beard, Phillip <Beard.Phillip@epa.gov>; Bingham, Kimberly <Bingham.Kimberly@epa.gov>; Hansen, Susan <Hansen.Susan@epa.gov>
Subject: Status on the Termination of the Seal Shield FIFRA SSURO

Andrew,

The Termination of the SSURO is currently in routing to be signed. However, the signing of the Termination will be delayed if the EPA is not in receipt of Seal Shield's certification of compliance. Before the EPA can terminate a SSURO, the company or person subject to the SSURO is required to submit a certification stating that they are in compliance

with the terms of the SSURO and the requirements of FIFRA. I previously requested that information from you in the email below sent on June 16th, 2020, and I also contacted Ed Schwartz, Seal Shield's outside counsel via telephone on June 17th to request that information.

Please forward Seal Shield's certification of compliance to the EPA as soon as possible.

With regards,

Marlene Tucker | Office of Regional Counsel
US EPA- Region 4
Atlanta Federal Center
61 Forsyth Street, SW
13th Floor
Atlanta, Georgia 30303-8960
Office: 404.562.9536
Tucker.Marlene@epa.gov

From: Tucker, Marlene
Sent: Tuesday, June 16, 2020 10:44 AM
To: Andrew McCarthy <andrew@sealshield.com>; Ed Schwartz <ess@mseslegal.com>
Cc: Caplan, Robert W. <Caplan.Robert@epa.gov>; Beard, Phillip <Beard.Phillip@epa.gov>; Bingham, Kimberly <Bingham.Kimberly@epa.gov>; Hansen, Susan <Hansen.Susan@epa.gov>; Rubini, Suzanne <Rubini.Suzanne@epa.gov>
Subject: Status on the Termination of the Seal Shield FIFRA SSURO

Andrew,

In conjunction with OPP, we have completed our review of Seal Shield's user manual, the labeling and proposed efficacy claims for the ElectroClave. Based on our review, we have begun taking the necessary steps to terminate the SSURO.
Please submit a certification of compliance to the EPA stating that Seal Shield has taken all the necessary steps to come into compliance with the SSURO and the requirements of FIFRA.

Regarding the EPA's review of the labeling for the ElectroClave, Seal Shield will need to revise the label as follows:

- Remove the company number 93474;
- Insert the identifier "**EPA Est. No**" before the assigned number. The EPA Establishment number may appear on any suitable location on the label or immediate container; however, it must appear on the wrapper or outside container of the package if the number cannot be clearly read through the wrapper or container. 40 CFR § 156.10(f);
- Provide the name and address of the producer, registrant, or person for whom the product is produced. 40 CFR §156.10(a)(1)(ii);
- Provide a reference to the **directions for use** in accompanying leaflets or circulars, such as "See directions in the enclosed user manual which can be found …; and
- Use conventional U.S. standard units of measurement (also known as avoirdupois or imperial) on the label. Pesticide labels may also declare net contents in metric units (liters, kilograms, etc.), as long as U.S. units of measurement are declared (e.g., "Net

Contents: 1 gallon (3.785 liters)"). **It is not acceptable to declare net contents only in metric units, i.e., 16KG.**

Regarding the user manual for the ElectroClave, the EPA recommends that Seal Shield make the following revisions:

- Remove the word "*safe* "for the statement "*ElectroClave provides a* ***safe,*** *secure and fully automated;*"
- Place the statements: "*ElectroClave can disinfect a non-porous, hard surface device achieving a 99.9% reduction of MRSA, S.aureus, E. coli, and CRE;*" and "*The ElectroClave will not penetrate inorganic and organic matter"* together under the same section to provide the user with a more comprehensive understanding of the effectiveness of the device;
- Move the "***Guidelines for Use- Cleaning and Disinfection***," section towards the beginning of the user manual since this is an extremely critical part of the manual and also identify specific examples of "***inorganic and organic materials***" to provide clarity to the user; and
- Provide specific examples of "***non-critical medical devices***" to provide clarity to the user.

We will continue to keep you posted on the status on the issuance of the SSURO termination notice.

With Regards,

EPA United States Environmental Protection Agency
Marlene Tucker | Office of Regional Counsel
US EPA- Region 4
Atlanta Federal Center
61 Forsyth Street, SW
13th Floor
Atlanta, Georgia 30303-8960
Office: 404.562.9536
Tucker.Marlene@epa.gov

CONFIDENTIALITY NOTICE: This message is intended exclusively for the individual(s) or entity(s) to whom or to which it is addressed. This communication may contain information that is proprietary, privileged, pre-decisional, confidential or otherwise legally exempt from disclosure. If you are not the named addressee, you are not authorized to read, print, retain, copy, or disseminate this message or any part of it. If you have received this message in error, please notify the sender immediately by e-mail and delete all copies of the message.