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**From:** Dimitri.Karakitsos@hklaw.com [Dimitri.Karakitsos@hklaw.com]  
**Sent:** 6/16/2017 8:46:28 PM  
**To:** Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]  
**Subject:** FW: FYI for call today

FYI this is what I sent over to Byron today. I believe this is the language the regional folks are interpreting to mean the labels have to be identical.

**(4) Placement of Label -**

**(i) General.** The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

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**From:** Karakitsos, Dimitrios J (WAS - X75132)

**Sent:** Friday, June 16, 2017 11:07 AM

**To:** 'Brown, Byron' <brown.byron@epa.gov>; 'traylor.patrick@epa.gov' <traylor.patrick@epa.gov>

**Subject:** FYI for call today

Gentlemen,

Happy Friday and appreciate you all making some time for us this afternoon. Just wanted to give you both a heads up on what Bissel is thinking after having a lot of internal discussions. Look forward to the discussion and please let me know if I can be of help with anything.

Thanks!

1. Beyond Adding a Second EPA Establishment Number, the Products are Not Misbranded  
Region 10 has interpreted 40 CFR 156.10(a)(4) to require that the labels on interior bottle and exterior box be an exact match; that interpretation is not supported by the FIFRA statute or regulations.

2. EPA HQ has Enforcement Discretion and, if necessary, can issue a No Action Assurance letter applicable to defined products and lots not specific to BISSELL (particularly where there is no risk to human health or the environment).

Discussion of Point 1: Beyond the addition of a second EPA establishment number (to reflect that the antibacterial cleaning solution, which was manufactured in Grand Rapids, was placed into a box in China), BISSELL contends that the products are not misbranded.

Region 9 cites 40 CFR 156.10(a)(4) as the basis for its misbranding allegation. 40 CFR 156.10(a)(4) requires that a pesticide label be securely attached to the outside of a box or package when the label on the immediate pesticide product container cannot be read through the box; it does not say that the pesticide label on the exterior of the box must be an exact match to the label on the pesticide bottle within. 40 C.F.R. 156.10(a), reproduced below, describes the elements that must be on a pesticide label. BISSELL maintains that the label on the exterior of the box meets all of the required elements of 40 CFR 156.10(a) and consists of language that is approved on the EPA Master Label for the product. Accordingly, the products (once the second EPA establishment number is added) are not misbranded.

**40 CFR 156.10(a)**

**(1) Contents of the label.** Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this part. The contents of a label must show clearly and prominently the following:

- (i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;
- (ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;
- (iii) The net contents as prescribed in paragraph (d) of this section;
- (iv) The product registration number as prescribed in paragraph (e) of this section;
- (v) The producing establishment number as prescribed in paragraph (f) of this section;
- (vi) An ingredient statement as prescribed in paragraph (g) of this section;
- (vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards.
- (viii) The directions for use as prescribed in paragraph (i) of this section; and
- (ix) The use classification(s) as prescribed in paragraph (j) of this section.

Discussion of Point 2: If necessary, EPA HQ has enforcement discretion and may issue a “No Action Assurance” letter, identifying the particular product and lot number information for the covered products. BISSELL would add an additional EPA establishment number to any boxes requiring it, but BISSELL would be able to sell and distribute products in the defined set without other relabeling. The no action assurance letter could be drafted to apply to the specific products and lots at issue rather than to BISSELL itself, thereby applying to the product rather than a particular party.

In response to possible state enforcement concerns, BISSELL’s believes this is just a theoretical risk and one for which BISSELL will bear the cost of any consequence to its customers under its indemnity agreements with its customers. A no action assurance letter from EPA related to federal enforcement under FIFRA has no bearing on state enforcement of state law and Bissell believes EPA should take action based on federal laws within their prevue rather than possible concerns with state laws.

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