

May 22, 2017

Mr. Ryan Jackson
Chief of Staff
Office of the Administrator 1101A
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
ryan.jackson@epa.gov

Re: BISSELL Matter in Region 9

Dear Mr. Jackson,

Please excuse me for directly reaching out to you, but my company, BISSELL Inc., has an urgent, time sensitive issue involving the EPA that needs intervention to avoid significant commercial losses for no health or safety reason. I'm happy to discuss the matter in greater length, but here is a little background.

BISSELL, a 140-year-old company based in Grand Rapids, Michigan, manufactures deep cleaning machines that are co-packaged with sample-sized bottles of an antimicrobial cleaning solution. Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), antimicrobial products are considered pesticides. Our product is registered as such with EPA's Office of Pesticide Programs (OPP). Please note that BISSELL is one of the Twenty-four companies to receive the EPA's Safer Choice Partner of the Year award for 2016.

The sample bottles of antimicrobial cleaning solution are manufactured in Grand Rapids, then shipped to China where our deep cleaning machines are manufactured. The co-packing occurs in China. Under EPA regulations, the manufacturing facility must have an EPA establishment number which must be displayed on the product packaging. BISSELL has establishment numbers for both the Grand Rapids facility and the facility in China. We made the mistake of putting the Grand Rapids facility's establishment number on the product that was imported to the U.S. from China. In early April, Customs and Border Protection (CBP) correctly flagged this to EPA and held the product in early April, and the imports were quarantined.

For a full month thereafter, BISSELL could not get information from EPA regarding the Agency's specific concerns; despite asking numerous times for information on how to get the products released, BISSELL did not get a substantive response from a Region 9 attorney until May 10, 2017. BISSELL has been prepared to add a sticker to the product cartons with a corrected establishment number, but EPA would never agree that this step will satisfy their concerns.

As we have waited for direction, the number of quarantined products has grown, and will pass 50,000 this week. BISSELL's supply chain has run dry and we are under extreme pressure to fulfill obligations to our customers. One large retail promotion beginning June 1 will fail badly if product in quarantine is not released immediately, and a substantial TV and digital advertising spend will be wasted if inventory is not available for distribution. These marketing programs are vital to BISSELL's business.

Finally, last Wednesday, Region 9 staff clarified its expectation that BISSELL must re-face a side panel section on every carton of the quarantined products. Their concern has nothing to do with product safety or protecting the environment; instead, they are strictly construing a regulation to require an expensive, time-consuming change to product labels that will be of no consequence to US consumers or the public.

Here's the problem Region 9 took six weeks to identify: Consistent with pesticide regulations, the product cartons show an exact replica of an EPA approved label for the antimicrobial cleaning solution, but as Region 9 now points out, that replica is not of the sample-sized bottle packed into the box, but of a larger bottle of the same antimicrobial cleaning solution.

Just to be clear: both the label on the sample bottle in the carton, and the label depicted on the side of the machine carton, are EPA-approved versions from the same antimicrobial Master Label. But Region 9 says it is "misbranded" because the labels are not one in the same. David Kim, an attorney at Region 9, asserted in his email of Friday, May 19 that 40 C.F.R. section 156.10(a)(4) requires BISSELL to duplicate the exact label from the bottle inside the box onto the carton label outside of the box. In his view, another EPA approved label for the same antimicrobial product does not satisfy that regulation.

So what is the difference between the two labels triggering this supposed "misbranding" violation? The use instructions for the anti-microbial cleaning solution are not identical. The version shown on the carton has this EPA-approved language:

1. After adding water, fill tank to Easy Fill formula line
2. Deep clean carpet following machine's user guide
3. Flush machine with clean water after use
4. Stay off cleaned area until completely dry and vacuumed

Meanwhile, the version on the trial-sized bottle enclosed in the box has these directions for use, which also have been previously approved by the EPA:

1. Vacuum thoroughly to remove loose dirt.
2. For best results removing tough stains, use a BISSELL Pretreat before deep cleaning.
3. Fill measuring cup provided or fill tank to formula fill lines.
4. Deep clean carpet following machine's user guide.
5. Flush machine with clean water after use.
6. Stay off cleaned area until completely dry and vacuumed.

Region 9 takes the position that adding lines 1. and 2. to the directions on the sample bottle, and not using the same exact words to instruct how to pour the cleaning solution into the machine, justifies a major misbranding enforcement action as well as holding all product shipments until BISSELL has manually relabeled all products according to these demands.

But note: these label differences are immaterial. No one at Region 9 is suggesting that they create any risk of harm to our ecology, or to any potential consumer, or the public at large.

BISSELL is being told to absorb enormous costs and a very expensive further delay to accomplish no public benefit, with no net effect on the health and safety of any product user or anyone else. All to replace one EPA-approved label for another.

We spoke on Friday with Kathleen Johnson, Region 9 Enforcement Director, and she has chosen to support her staff. Her stated position was that she did not have or wish to exercise the discretion to allow BISSELL to distribute products not strictly complying with all regulations.

We know, however, that EPA has this inherent discretion, and is authorized to craft a reasonable, rational approach to enforcing its regulations. Certainly if we had more time – had BISSELL been told to make this carton change three weeks ago, for instance – the position Region 9 is taking now could have worked, as this correction would have been finished by now and our products would be back into distribution in time to meet our commercial obligations. But at this point, BISSELL doesn't have more time.

We are urging you to exercise your discretion to adopt a common sense approach to resolving this matter. We will take every reasonable step necessary to bring newly produced units into exact alignment with respect to the on-carton label instructions; but with respect to the 50,000+ boxes currently in quarantine or already on their way to the US, we are asking for you to release the quarantine and allow for distribution once the establishment number is corrected.

As I stated, there are no health and safety issues at stake, BISSELL is not trying to skirt responsibility for mistakenly affixing the wrong facility's establishment number. We are simply seeking an appropriate resolution that meets our urgent and reasonable commercial needs.

We very much appreciate your attention to this matter. Please call me if you should have any questions or wish to discuss the matter further.

Very truly yours,

James A. Krzeminski
President, BISSELL North America

Cc:

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