



5001 Campus Drive  
College Park, MD 20740

March 23, 2018

Tony Salemi  
CEO and President  
MicrobeGuard Corporation  
1901 Greenleaf Ave  
Elk Grove Village, IL 60007 US

#546971

Dear Mr. Salemi:

The purpose of this letter is to inform you that the use of silver ions in your FoodTouch® paper products requires approval from the U.S. Food and Drug Administration (FDA). Your product website references food contact applications for lining food trays, interleaving stacked food, and wrapping individual food products<sup>1</sup>. Your website also refers to your FoodTouch® products as “antimicrobial.” We have determined that silver ions may migrate from your products (items #FT-24 and #FT-1016x2) into food, and therefore, as explained below, the silver ions used in your products are food additives and require FDA approval.

As background, any substance that is reasonably expected to become a component of food is a food additive that is subject to premarket approval by FDA, unless the substance is generally recognized as safe (GRAS) among experts qualified by scientific training and experience to evaluate its safety under the conditions of its intended use, or meets one of the other exclusions from the food additive definition in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the Act). Manufacturers are responsible for ensuring that their products comply with applicable legal requirements.

Food additives that are reasonably expected to become a component of food from their food contact use, but do not have a technical effect in the food, may be authorized by an effective food contact notification (FCN)<sup>2</sup> or by a food additive regulation for indirect additives. Food additives that are intended to have a technical effect in food are considered direct additives and require a food additive regulation authorizing this use. An antimicrobial effect on food is a technical effect. We are not aware of authorizations for the use of silver ions in your product either for direct additive use, or, in the absence of an intended technical effect, for food contact use. We are also not aware of a basis to conclude that silver ions are GRAS for this use or is otherwise exempt from being regulated as a food additive.

Thus, for your use of silver ions in the FoodTouch® antimicrobial food paper products to be lawful, it requires food additive approval. More specifically, because the silver ions appear to

have a technical effect in the food by extending shelf life through its antimicrobial properties, the substance requires a food additive regulation authorizing this use. Your unauthorized use of the

<sup>1</sup> <http://www.microbeguard.com/index.php/products/foodtouch/products> (last accessed March 16, 2018).

<sup>2</sup> See FDA’s inventory of effective FCN’s at <https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN>

silver ions in your FoodTouch® antimicrobial food paper products renders your product adulterated under section 402(a)(2)(C) of the Act [21 U.S.C. § 342(a)(2)(C)]. To seek a food additive regulation for this use of the silver ions, you would need to submit a food additive petition to the Division of Petition Review in the Office of Food Additive Safety. Detailed information and guidance on the food additive petition process are available on our Internet site, <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/default.htm>.

It is your responsibility to ensure that all products marketed by your company comply with the FD&C Act and FDA's implementing regulations. You should take prompt action to correct the violations described above and prevent their future recurrence.

Please respond in writing to this letter within 30 working days of receipt with the actions you plan to take in response to this letter. Please direct your reply to Rob Genzel Jr., Compliance Officer, Division of Enforcement (HFS-608), 5001 Campus Drive, College Park, MD 20740, or e-mail [rob.genzel@fda.hhs.gov](mailto:rob.genzel@fda.hhs.gov).

Sincerely,

/s/

Sabina Reilly  
Director  
Division of Enforcement (HFS-605)  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition