DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

September 29, 2010

Gary Burin
Senior Managing Toxicologist
Technology Sciences Group, Inc.
1150 18th Street, NW, Suite 1000
Washington, DC 20036

Re: Food Contact Substance Notification FCN 001011

Dear Mr. Burin:

This is in reference to your notification for the food-contact substance and use described as follows:

Food Contact Substance (FCS)
An aqueous solution of chlorine dioxide (CAS Reg. No. 10049-04-4).

Notifier
CDG Environmental, LLC

Manufacturer/supplier
CDG Environmental, LLC

Intended Use
As an antimicrobial agent used in poultry processing, and to wash fruits and vegetables that are not raw agricultural commodities, in an amount not to exceed 3 parts per million residual chlorine dioxide as determined by Method 4500-ClO2-E in the "Standard Methods for the examination of Water and Wastewater 20th ed. 1998", or an equivalent method.

Limitations/Specifications
The chlorine dioxide is manufactured by passing a mixture of chlorine gas and air, or chlorine gas and nitrogen gas, through a column of granules composed of sodium chlorite and other salts that are generally recognized as safe.
The generator effluent contains at least 90 percent by weight of chlorine dioxide with respect to all chlorine species as determined by Method 4500-ClO2-E (above).
Treatment of the fruits and vegetables with chlorine dioxide shall be followed by a potable water rinse, or by blanching, canning or cooking.

This is to inform you that as of October 28, 2010, FCN 01011 will become effective. It will be added to the list of effective notifications for food contact substances available on the agency's internet site in the *Ingredients and Packaging* section under the *Food* topic of www.fda.gov.

The agency has determined that allowing this notification to become effective will not have a significant impact on the quality of the human environment and therefore an environmental impact statement is not required. The agency's finding of no significant impact and the evidence

supporting that finding, contained in an environmental assessment, will be publicly available after the effective date of the notification.

This effective notification is applicable only to aqueous solutions of chlorine dioxide manufactured, as described above, by CDG Environmental, LLC and is limited to the use of the food-contact substance also identified above. You should inform the agency of any modification in the food-contact substance limitations/specifications given in the notification or of any alteration in the manufacturing process that would result in a change in the impurities in the food-contact substance. Such changes may require submission of a new notification.

The existence of an effective notification for a food-contact substance does not relieve use of the subject substance from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act (FFDCA) or with Title 21 CFR §174.5 *General provisions applicable to indirect food additives*. For example, in accordance with section 402(a)(3) of the Act, use of the food contact substance should not impart odor or taste to food rendering it unfit for human consumption. If new data or information become available to FDA demonstrating that the intended use of the food contact substance is no longer safe, the agency will inform you of its determination that the intended use of the food-contact substance is no longer safe. In addition, if you become aware of data that raise questions about the safety of the intended use of the food contact substance, you should notify the agency immediately and be prepared to supply data necessary to resolve the questions.

Section 301(ll) of the FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, a biological product licensed under section 351 of the Public Health Service Act or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(ll) or any of its exemptions apply to the intended use of the food-contact substance. Accordingly, allowing this FCN to become effective should not be construed as a statement that the intended use of the food-contact substance would not violate section 301(ll).

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Mark Hepp
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition