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BOSTON NEW YORK SAN FRANCISCO WASHINGTON, DC 0988 '03 APR -4 11:18

April 4, 2003

Mark A. Greenwood
202-626-3905

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comment on Food Facility Registration (Docket No. 02N-0276)

To Whom It May Concern:

On behalf of UOP LLC, we are providing these comments on the proposed rule issued by the Food and Drug Administration (FDA) on February 3, 2003 (68 Fed. Reg. 5378) concerning the registration of facilities that manufacture, process, hold or pack food for consumption in the United States under Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act.)

UOP LLC is a major manufacturer of a class of inorganic chemicals known as synthetic zeolites. Due to their unique characteristics, zeolites are used by our customers in a wide variety of applications to adsorb trace chemicals from liquids and gases. The primary applications of our product occur in the industrial or commercial manufacturing sectors, but UOP does supply zeolites to customers in the food packaging industry. The primary purpose of the zeolite in these applications is to adsorb odor-causing molecules emitted from food packaging or to adsorb ambient moisture to protect food integrity. UOP supplies zeolites to meet customer specifications but the chemical is only a minor component to the overall food packaging system.

While UOP has supplied zeolites to customers for use as a component of food packaging, the company does not directly manufacture food packaging. Our products must meet quality standards, specified by our customers, to serve their intended uses. UOP's customers have not historically required UOP to meet any FDA requirements for food packaging related to our manufacturing operations. Similarly, UOP's manufacturing facility has never been subject to FDA or USDA registration requirements due to this minor application of our zeolite products in food packaging.

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This proposed rule suggests that FDA will interpret very broadly the scope of the registration requirement under the Bioterrorism Act. In particular, the preamble to the rule suggests that the rule covers "immediate food packaging or components of immediate food packaging that are intended for food use."¹ A possible reading of this language would require a company like UOP to register its entire zeolite manufacturing operation simply because its product may, on occasion, become a small portion of a food packaging material.

UOP does not believe that the registration of a facility such as its zeolite manufacturing plant is compelled by law or warranted as a matter of public policy. The use of small amounts of zeolites as an adsorbent in food packaging does not present a realistic scenario for attack on the U.S. food supply by terrorists. We cannot believe that Congress intended FDA to sweep a large array of industrial chemical manufacturers within the Bioterrorism Act's registration requirements for food facilities.

It is worth noting that the Bioterrorism Act's registration requirements do not apply to a large universe of establishments, including restaurants, farms and retail facilities, that have direct contact with food for human consumption on a daily basis. We can only assume that these exemptions reflect a Congressional determination that the registration requirement should remain practical from an administrative perspective and targeted at establishments that present the greatest potential risk. In this context, it seems particularly unlikely that Congress would have intended that FDA register conventional inorganic chemical manufacturing plants as food facilities.

From a public policy perspective, the costs of registering inorganic chemical manufacturing plants as food facilities under the Bioterrorism Act would be wholly out of proportion to the potential risks of terrorism that might be avoided. This interpretation of the Act would greatly expand FDA's administrative and oversight obligations for a wide array of industrial facilities that produce small components of food packaging. Such a result can only dilute the effectiveness of FDA in focusing its resources on the more credible threats to the U.S. food supply.

UOP urges FDA to clarify, either through an explicit exemption or modification of the definitions used in the rule, that manufacturing facilities producing components of food packaging need not be registered under the program.

¹ 68 Fed. Reg. 5382.

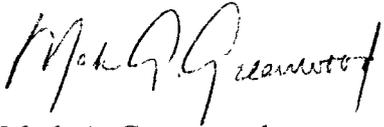
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Thank you for this opportunity to comment, and we would be happy to respond to any questions you may have about this matter.

Best regards,

A handwritten signature in black ink that reads "Mark A. Greenwood". The signature is written in a cursive style with a large, stylized initial "M".

Mark A. Greenwood