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March 28, 2012

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

I write to urge you to quickly move to finalize long overdue regulations to curb the use of triclosan in consumer products. Just yesterday, the Canadian federal government announced its finding that the antimicrobial chemical triclosan is toxic to the environment. In 2006, Environment Canada, the Canadian equivalent to the Environmental Protection Agency (EPA), called for a safety assessment of triclosan under the government's Chemical Management Plan. Completion of the draft assessment, which occurred this week, concluded that triclosan was toxic to the environment. This designation triggers risk management steps, including a potential ban in a range of personal care products, which will be taken by the Canadian government to protect people and the environment. In contrast, the Food and Drug Administration (FDA), has for nearly 40 years, failed to finalize its regulations regarding use of triclosan in consumer hand soaps and sanitizers, despite abundant questions about the human health risks and effectiveness of this chemical.

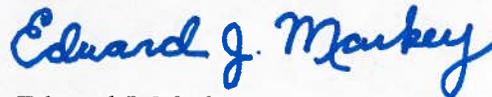
Triclosan was originally introduced in the healthcare setting as a surgical scrub, but over the last decade its use has proliferated. Triclosan is currently used in 75 percent of all liquid hand soaps and is also prevalent in kitchenware, cosmetics, children's toys and countless other items Americans handle everyday. In fact, studies by the Centers for Disease Control and Prevention (CDC) found triclosan in 75 percent of all Americans and the concentration of this chemical increased by more than 40 percent in all age groups when data from 2004 was compared to data from 2006. The FDA's rulemaking – called a monograph – which was first drafted in 1972, would establish conditions and labeling requirements under which over-the-counter (OTC) topical antiseptic drug products (including consumer products that contain antibacterial ingredients such as triclosan) would be safe and effective.

In response to my December 22, 2010 letter, the FDA indicated in February 2011 that it was undergoing a thorough review of triclosan and updated its website in April 2010 in an effort to keep the public aware of the status of this review and FDA's ongoing

regulatory process. As a part of that update, FDA stated that it is “working to incorporate the most up-to-date data and information into the regulations that govern the use of triclosan in consumer products.” That website update indicated that FDA would communicate its findings in spring 2011. After this deadline passed, FDA updated its website to say it would communicate findings in winter 2012, with no further explanation as to the reason for the delay, or status update.

Given this significant delay and the Canadian government’s recent decision on triclosan, I request that you provide a full and complete response that details the actions that FDA has taken in the last 12 months to finalize its regulations on over-the-counter products that use triclosan, and provide a detailed timeline regarding your efforts to finalize these long-overdue regulations. Please provide this response no later than April 17, 2012. Should you have any questions about this request, please have your staff contact Dr. Avenel Joseph in my office at (202) 225-2836.

Sincerely,



Edward J. Markey