



APR 19 2006

Jay Feldman  
Beyond Pesticides  
701 E Street, S.E. Suite 200  
Washington DC 20003

Re: Docket No. 2005P-0432/CP 1

Dear Mr. Feldman:

This letter is in response to your citizen petition (CP 1), dated October 25, 2005, in which you requested that the Food and Drug Administration (FDA) ban all non-medical uses of triclosan, also known as Irgasan. You provided a number of arguments as to why you believe that triclosan's continued registration will result in dangerous consequences for public health and the environment.

In accordance with 21 CFR 10.30(e)(2)(iii), this letter is to advise you that FDA has not reached a decision on your petition within 180 days of filing of the petition. Your petition raises three types of issues that fall under different regulatory jurisdiction, as described below. We would like you to clarify the nature of your request, specifically what is meant by "non-medical uses" of triclosan. This information is needed so that we may respond to your request appropriately.

Your petition references studies that examined triclosan-containing dishwashing liquid or antibacterial-containing cleansers. The use of triclosan-containing products to clean surfaces or objects can be considered a non-medical use. Products that are used on hard, inanimate surfaces or objects to destroy or inactivate infectious microorganisms are considered disinfectants and are regulated by the U. S. Environmental Protection Agency (EPA). Concerns regarding triclosan-containing surface cleaners should be directed to the EPA.

Your petition also refers to the October 20, 2005, Nonprescription Drugs Advisory Committee meeting regarding the efficacy of antibacterial soaps and washes. Antibacterial soaps and washes that are used to reduce bacteria on the skin (i.e., antiseptics) have medical uses and are considered drugs, which are regulated by FDA in the Center for Drug Evaluation and Research (CDER).

The mission of CDER is to assure that safe and effective drugs are available to the American people. To do this, the safety and efficacy of drugs are reviewed through the New Drug Application (NDA) process or through the over-the-counter (OTC) drug review. As a part of the drug review process, drug manufacturers are required to perform

environmental assessments of their drug products. These environmental assessments are taken into account during CDER's determination of the safety of a drug.

Triclosan is also found in cosmetics, which are regulated by FDA's Center for Food Safety and Applied Nutrition (CFSAN). According to the Cosmetic, Toiletry, and Fragrance Association's International Cosmetic Ingredient Dictionary and Handbook (11<sup>th</sup> edition, 2006), triclosan functions as a cosmetic biocide, deodorant agent, and preservative. Although premarket approval of cosmetic products or ingredients is not required, FDA has a free voluntary registration program for cosmetic product information that includes the filing of cosmetic ingredient information (requested to be listed in descending order of predominance). According to information in our database, triclosan has been used as an ingredient in skin cleansers, body lotions, deodorants, shaving preparations, bath products, makeup products, and fragrance preparations.

Please provide the clarification of the intent of your request, or address any additional questions regarding this matter, by referring to the docket number noted above and submitting all materials through any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow instructions for submitting comments on the agency Web site.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Sincerely yours,



Steven K. Galson, M.D., M.P.H.

Director

Center for Drug Evaluation and Research