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Congress of the United States

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January 5, 2010

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 request information regarding the Food and Drug Administration's (FDA's) plans to finalize its regulation of over the counter (OTC) topical antiseptic drug products, including soaps and hand sanitizers, which was first proposed a startling 37 years ago. The rulemaking – in the form of a monograph – would establish conditions and labeling under which OTC topical antiseptic drug products would be safe and effective. In 1972, FDA first proposed a rulemaking for these products to ensure that they are generally regarded as safe and effective and not mislabeled. In 1978, a draft rule was published in the Federal Registrar and opened for public comment. Over 35 years later, although the draft rule has been revised and reopened several times for comments, it has never been finalized. This pace of activity on the part of FDA is especially perplexing in light of advances in science that question both the effectiveness and safety of certain antimicrobial agents, and that indicate that their widespread use may increase antibiotic resistance and have complex endocrine disrupting effects. I am concerned that by failing to finalize the proposed rule, FDA has allowed the use of chemicals in everyday antiseptic agents that may be both ineffective and unsafe to human health and the environment, and I urge you to make a final determination regarding these products as expeditiously as possible.

As you may know, triclosan was originally introduced in the healthcare setting as a surgical scrub, but over the last decade there has been a rapid increase in the use of both triclosan, and a related compound triclocarban, in a number of consumer products including soaps, handwashes, toothpaste, shave gels, kitchenware, clothes, and toys. Over 95% of the uses of these antimicrobial agents are in consumer products that are disposed of in residential drains.[1] This is of particular concern in today's health climate in which these "antibacterial" products are

[1] Reiss, R., N. Mackay, C. Habig, and J. Griffin. 2002. *An ecological risk assessment for triclosan in lotic systems following discharge from wastewater treatment plants in the United States.* Environmental Toxicology and Chemistry, 21(11): 2483-2492.

extensively used by healthy individuals as a safeguard against the H1N1 and seasonal flu viruses.[2]

Since wastewater treatment plants are not required to remove triclosan and triclocarban from the water and these compounds are highly stable for long periods of time, it is reasonably expected that people could be further exposed to these compounds by drinking contaminated water. In fact, a 2006 study by the Johns Hopkins Bloomberg School of Public Health found that about 75 percent of triclosan makes it through water treatment methods, ending up in our surface water and in municipal sludge, which is regularly applied to U.S. crop fields as a fertilizer.[3] Additionally, a U.S. Geological Survey (USGS) report found that between 1999 and 2000, triclosan was found in nearly 60% of U.S. streams.[4] This means there is a potential risk of these chemicals accumulating in both our drinking water and our foods. This risk is demonstrated by a recent study by the Centers for Disease Control and Prevention (CDC), which found triclosan in the urine of 75% of Americans, including children.[5]

Despite their widespread use, there is little data to prove that products containing triclosan and triclocarban are more effective in protecting against symptoms of viral infections than using regular soap and water with proper hand-washing techniques. In fact, guidance provided by an FDA advisory panel in 2005 stated that antibacterial soaps and washes are no more effective at preventing illness than plain soap and water.[6]

Moreover, recent scientific evidence suggests that these substances may act as endocrine disruptors causing adverse health effects on the endocrine system when used over sustained

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[2] Beyond Pesticides *The Ubiquitous Triclosan*, Aviva Glaser(beyondpesticides.org) Vol. 24, No. 3, 2004 Examples of soaps containing triclosan are: Dial® Liquid Soap; Softsoap® Antibacterial Liquid Hand Soap, CVS Antibacterial Soap, Dawn® Complete Antibacterial Dish Liquid, Ajax® Antibacterial Dish Liquid; In June 2009, FDA warned against marketing fraudulent virus claims: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm166801.html (Jun 15, 2009)

[3] Heidler J, Sapkota A, Halden RU.2006. *Partitioning, Persistence, and Accumulation in Digested Sludge of the Topical Antiseptic Triclocarban during Wastewater Treatment.* Environmental Science and Technology, 40(11):3634-9.

[4] Rolf U. Halden and Daniel H. Paull. 2005. *Co-Occurrence of Triclocarban and Triclosan in U.S. Water Resources*. Environmental Science and Technology, 39(6):1420–1426.

[5] Calafat AM, Ye X, Wong LY, Reidy JA, Needham LL. 2008. *Urinary concentrations of triclosan in the U.S. population: 2003-2004*. Environmental Health Perspectives, 116(3):303-7.

[6] http://www.webmd.com/news/20051020/fda-panel-no-advantage-to-antibacterial-soap

periods of time.[7] Studies using animal models suggest that triclosan can be absorbed into the body via dermal exposure. Additionally, studies using triclosan have shown that it interferes with thyroid hormone, which is vital for proper development of the brain and nervous system in fetuses, infants, and children, and regulates energy balance in adults. Triclocarban has also been shown to interfere with thyroid hormone as well as estrogens and androgens. These studies raise questions regarding the safety of using these chemicals in consumer products.

Finally, the use of consumer antiseptics may be associated with a number of adverse consequences. There is some scientific evidence that suggests use of triclosan and other antimicrobial agents may increase widespread antibiotic resistance, further raising questions regarding the safety of these products.[8]

In order to better understand FDA's plans and progress in this proposed rulemaking, I ask for your prompt response to the following questions.

1. What is the status of the final monograph rulemaking? When does FDA plan on promulgating finalized rules regarding over the counter topical antimicrobial products? Please provide a detailed timeline.

2. In your 1994 Tentative Final Monograph, you say that:

   'The agency sees no reason to continue to include ``antimicrobial soap'' as a separate product category. Soap is considered to be a dosage form, and specific dosage forms are not being included in the monograph unless there is a particular safety or efficacy reason for doing so. Antimicrobial ingredients may be formulated as soaps for some of the uses discussed in this document, e.g., handwash; however, the designation ``antimicrobial soap'' is no longer being proposed for inclusion in the monograph.'

   What products are covered by the monograph? Please provide a detailed list. How would the agency treat a handsoap or bodywash that makes an antibacterial claim? If these products are not subject to the monograph, please provide a rationale, in light of the

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[7] See, for example, Kumar V, Chakraborty A, Kural MR, Roy P. 2009. *Alteration of testicular steroidogenesis and histopathology of reproductive system in male rats treated with triclosan.* Reproductive Toxicology 27(2):177-85 and Kevin M. Crofton, Katie B. Paul , Michael J. DeVito, Joan M. Hedge. 2007. *Short-term in vivo exposure to the water contaminant triclosan: Evidence for disruption of thyroxine*. Environmental Toxicology and Pharmacology, 24:194–197.

[8] See for example: Aiello AE, Larson EL, Levy SB. 2007. *Consumer antibacterial soaps: effective or just risky?* Clinical Infectious Diseases, 45:S137–S147.

evidence that these agents may be both ineffective and unsafe. Has the FDA concluded that there is no particular safety or efficacy reason for treating these products separately?

3. Has the FDA reviewed the scientific evidence regarding the endocrine disrupting nature of triclosan and triclocarban? If yes, what has the FDA concluded? If not, why not?

4. Has the FDA itself assessed the low dose, long term health and environmental impacts of these compounds? If yes, what, if anything, has the FDA concluded? If not, does FDA plan to do so?

5. Would FDA proceed differently with its rule-making for these products if it determines that the route of human exposure to triclosan or triclocarcan is through ingestion of contaminated drinking water, and not through dermal absorption during the course of its intended use? Please explain.

6. In 2008, the Environmental Protection Agency (EPA) Re-registration eligibility decision (RED) document required label changes to reflect the environmental hazards posed by end-use products such as pesticides that contain triclosan. This labeling requirement states:

> *"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authorities are notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."*

Given the fact that triclosan used in products under FDA's jurisdiction are consistently washed down the drain and into sewage treatment systems, do you think that personal products should be similarly labeled? Why or why not?

7. The National Environmental Policy Act (NEPA) requires all federal agencies, including FDA, to assess the environmental impacts of any proposed actions. Has the FDA performed an environmental assessment, or prepared a detailed statement of environmental impact, on the use and disposal of these antimicrobial agents, as it has for other products such as prescription drugs? If so, please provide a copy, and if not, why not?

8. Has the FDA evaluated the efficacy of antiseptic washes used by consumers in reducing transmission of infection? Has the FDA determined that use of antiseptic handwashes is

superior to washing hands with regular soap using proper handwashing techniques? If so, please describe the manner in which this determination was made.

9. What percentage of consumer "antibacterial" soaps, including liquid and bar soaps contain triclosan or triclocarban?

10. To what extent has the FDA evaluated the claim that some anti-microbial products may increase anti-biotic resistance? Has the FDA completed or does it plan to complete a thorough survey of the published literature to determine whether antibiotic resistance has been reported for triclosan and triclocarban? Does FDA plan to consider this potential impact in its consideration of whether these products are safe and effective? Why or why not?

11. Will the FDA's proposed rulemaking regulate chemicals used in consumer handwashes differently than those marketed for and used by health care professionals? Please explain.

Thank you for your assistance and cooperation in this matter. I request that you provide a full and complete response within 15 working days or no later than January 26, 2010. Should you have any questions about this request, please have your staff contact Dr. Avenel Joseph or Dr. Michal Freedhoff of my staff at (202) 225-2836.

Sincerely,

Edward J. Markey
Chairman
Subcommittee on Energy and Environment

cc: The Honorable Henry A. Waxman
Chairman

The Honorable Joe Barton
Ranking Member

The Honorable Fred Upton
Ranking Member
Subcommittee on Energy and Environment