U.S. Food and Drug Administration
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FDA News Release

FDA requests additional information to address data gaps for consumer hand sanitizers

Proposed rule focuses on certain active ingredients in antiseptic hand sanitizers and wipes used in the consumer setting

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Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm509302.htm)

The U.S. Food and Drug Administration today issued a proposed rule requesting additional scientific data to support the safety and effectiveness of certain active ingredients used in topical consumer antiseptic rubs (including hand sanitizers) marketed over-the-counter (OTC). The FDA's request for more data is intended to help the agency ensure that regular use of these products does not present unknown safety and efficacy concerns, and does not mean the FDA believes these products are ineffective or unsafe.

Antiseptic rubs are products that are intended to be used by consumers when soap and water are not available, and are left on and not rinsed off with water. Millions of Americans use antiseptic rubs daily, sometimes multiple times a day, to help reduce bacteria on their hands.

"Today, consumers are using antiseptic rubs more frequently at home, work, school and in other public settings where the risk of infection is relatively low," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "These products provide a convenient alternative when hand washing with plain soap and water is unavailable, but it's our responsibility to determine whether these products are safe and effective so that consumers can be confident when using them on themselves and their families multiple times a day. To do that, we must fill the gaps in

scientific data on certain active ingredients."

The CDC advises (http://www.cdc.gov/handwashing/) that washing hands with plain soap and running water is one of the most important steps consumers can take to avoid getting sick and to prevent spreading infections to others. If soap and water are not available, the CDC recommends using an alcohol-based hand sanitizer that contains at least 60 percent alcohol.

Based on new scientific information and input of outside scientific and medical experts on an independent **advisory committee (/AdvisoryCommittees/Calendar/ucm407136.htm)**, the agency is requesting additional scientific data to demonstrate that the active ingredients used in consumer antiseptic rubs are generally recognized as safe and effective to reduce bacteria on skin. The agency is requesting manufacturers provide data for three active ingredients – alcohol (ethanol or ethyl alcohol), isopropyl alcohol and benzalkonium chloride. Since 2009, 90 percent of all consumer antiseptic rubs use ethanol or ethyl alcohol as their active ingredient.

The proposed rule does not require any consumer hand sanitizer products to be removed from the market at this time. Instead, it requires manufacturers who want to continue marketing these products under the OTC Drug Review to provide the FDA with additional data on the active ingredients' safety and effectiveness, including data to evaluate absorption.

Since the FDA began review of topical antiseptics in the 1970s, many things have changed, including the frequency of use of some of these products, new technology that can detect low levels of antiseptics in the body, and the FDA's safety standards and the scientific knowledge about the impact of widespread antiseptic use. The proposed rule seeks to ensure that the agency's safety and effectiveness evaluations and determinations for these consumer antiseptic rub active ingredients are consistent, up-to-date and appropriately reflect current scientific knowledge and increasing use patterns.

The FDA is particularly interested in gathering additional data on the long-term safety of daily, repeated exposure to these ingredients by consumers, and on the use of these products by certain populations, including pregnant women and children, for which topical absorption of the active ingredients may be important. Emerging science also suggests that for some antiseptic active ingredients, systemic exposure (full body exposure as shown by detection of antiseptic ingredients in the blood or urine) is higher than previously thought, and that more information is needed about the effects of repeated daily human exposure to some antiseptic active ingredients.

Today's action is part of the FDA's larger, ongoing review of OTC antiseptic active ingredients to ensure these ingredients are safe and effective. The FDA has previously issued proposed rulemakings on consumer antiseptic washes (**December 2013 (/NewsEvents/Newsroom/PressAnnouncements/ucm378542.htm)**) and health care antiseptics (**April 2015 (/NewsEvents/Newsroom/PressAnnouncements/ucm445002.htm)**).

The proposed rule will be available for public comment for 180 days. Concurrently, companies will have one year to submit new data and information, and comments on any new data or information may then be submitted to the docket for an additional 60 days. The FDA will then evaluate the data and comments received in response to this

proposal. The FDA's final determination will be published as a final rule (final monograph).

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by helping to ensure the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for helping to ensure the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- Safety and Effectiveness of Consumer Antiseptic; Topical Antimicrobial Drug Products for Over-The-Counter Human Use; Proposed Amendment of the Tentative Final Monograph (https://federalregister.gov/a/2016-15410)
- CDC: Handwashing (http://www.cdc.gov/handwashing/)
- Topical Antiseptic Products: Hand Sanitizers and Antibacterial Soaps (/Drugs/DrugSafety/InformationbyDrugClass/ucm444681.htm)

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