

FDA Publishes Final Rule for Consumer Antiseptic Washes

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Food, Drugs, and Devices

Yesterday, FDA published its final rule regulating certain active ingredients found in over-the-counter (“OTC”) consumer antiseptic wash products that are intended to be used with water and rinsed off after use, such as hand or body washes, which FDA refers to as “consumer antiseptic washes” (the “Final Rule”).¹ In the Final Rule, FDA deems 19 active ingredients to be “nonmonograph,” meaning that they are not generally recognized as safe and effective (“GRAS/GRAE”). As a result, once the Final Rule becomes effective, OTC consumer antiseptic washes containing these active ingredients will be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act and constitute new drugs for which premarket approval is required. FDA has deferred further rulemaking for three active ingredients to allow for the development and submission of new safety and effectiveness data.

Background

The Final Rule regulating OTC consumer antiseptic washes is part of FDA’s ongoing rulemaking for OTC drug products marketed in the U.S. on or before May 11, 1972, commonly known as the “OTC Drug Review.” The Final Rule amends the tentative final monograph published in 1994 for OTC antiseptic drug products² and finalizes in part FDA’s proposed rule published in December 2013 regarding conditions under which OTC consumer antiseptic washes are GRAS/GRAE.³

FDA’s rulemaking for consumer antiseptic washes is part of a November 2013 Consent Decree following a Natural Resources Defense Council lawsuit pursuant to which FDA agreed to complete by specified deadlines certain topical antimicrobial drug product rulemakings involving triclosan.⁴

¹ 81 Fed. Reg. 61106 (Sept. 6, 2016).

² See 59 Fed. Reg. 31402 (June 17, 1994).

³ 78 Fed. Reg. 76444 (Dec. 17, 2013).

⁴ Consent Decree, *Nat. Resources Def. Council v. FDA*, No. 10-cv-05690 (S.D.N.Y.).

Highlights of the Final Rule

The Final Rule generally retains the same approach that FDA took in the December 2013 proposed rule and includes:

- **Covered products.** The Final Rule applies only to OTC topical consumer antiseptic products that are intended to be rinsed off with water, such as antibacterial soaps, hand washes, or body washes. The Final Rule does not cover consumer antiseptic rubs that are not rinsed off after use; health care antiseptics intended for use by health care professionals in a hospital or other health care settings; first aid antiseptics, such as skin wound cleansers; or antiseptic products used by the food industry.
- **Nonmonograph active ingredients.** With respect to the 19 active ingredients that the agency has found not to be GRAS/GRAE, the Final Rule reflects that FDA received no additional data since the December 2013 proposed rule, or the data and information it did receive were “insufficient” to support GRAS/GRAE findings. These 19 active ingredients are –
 - Cloflucarban
 - Fluorosalan
 - Hexachlorophene
 - Hexylresorcinol
 - Iodophors (i.e., iodine-containing ingredients)
 - Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)
 - Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
 - Nonylphenoxypoly (ethyleneoxy) ethanoliiodine
 - Poloxamer—iodine complex
 - Povidone-iodine 5 to 10 percent
 - Undecoylium chloride iodine complex
 - Methylbenzethonium chloride
 - Phenol (greater than 1.5 percent)
 - Phenol (less than 1.5 percent)
 - Secondary amylicresols
 - Sodium oxychlorosene
 - Tribromsalan
 - Triclocarban
 - Triclosan
 - Triple dye

Given the Final Rule’s determination that these active ingredients are not GRAS/GRAE, once the Final Rule becomes effective, these active ingredients will be “nonmonograph”

as consumer antiseptic wash products. As a result, they will be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act and constitute new drugs for which approved applications are required prior to marketing.

- **Deferred rulemaking for three active ingredients.** FDA is deferring regulatory action on benzalkonium chloride, benzethonium chloride, and chloroxylenol at the request of “interested parties” who plan to submit safety and effectiveness data for FDA consideration. Accordingly, the Final Rule does not discuss the regulatory status of these three active ingredients in OTC consumer antiseptic washes.
- **Clinical outcomes testing requirement.** Notably, despite strong objections from stakeholders, the Final Rule holds firm on FDA’s December 2013 proposal that clinical outcome studies are needed to support a GRAE determination for an active ingredient in a consumer antiseptic wash. Under this standard, a study must demonstrate a direct clinical benefit—in this case, a reduction in infection—from a consumer antiseptic wash, as compared to washing with nonantibacterial soap and water. Presumably, FDA will apply this standard to future GRAE determinations for the active ingredients that have been deferred.
- **Commercial food handler antiseptics.** The Final Rule clarifies that this rulemaking does not impact the regulatory status of antiseptics used by the food industry. FDA established a new category of antiseptics in its 1994 tentative final monograph on topical antimicrobial drug products and requested the submission of relevant data and information. In comments to the December 2013 proposed rule, stakeholders asked that FDA distinguish between consumer hand wash products and those used by commercial food handlers (e.g., in food processing, preparation, or handling). The Final Rule reflects FDA’s agreement that a separate category for commercial food handler antiseptics “is warranted because of additional issues raised by the public health consequences of foodborne illness, differences in frequency and type of use, and contamination of the hands by grease and other oils.”⁵ FDA plans to address commercial food handler antiseptics in a separate rulemaking and to conduct a “thorough evaluation” of the safety and effectiveness data for antiseptic active ingredients intended for this category of use.⁶

Effective Date

The Final Rule is effective September 6, 2017. On or after this date, any OTC consumer antiseptic washes containing an active ingredient found in the Final Rule not to be GRAS/GRAE or to be misbranded “cannot be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved new drug application.”⁷ FDA also states elsewhere in the Final Rule that products containing any of the 19 active ingredients that have been found not to be GRAS/GRAE must be reformulated or removed from the market by the effective date if they are not subject to an approved new drug application or an abbreviated

⁵ 81 Fed. Reg. at 61113.

⁶ *Id.*

⁷ *Id.* at 61125.

new drug application.⁸ The Final Rule explains that the effective date was established with the recognition “that manufacturers would need time to comply with this final rule” due to the scope of products that are subject to the regulation.⁹

Covington & Burling LLP is experienced in advising clients on matters related to OTC drug products, including consumer antiseptic washes, and the OTC Drug Review. If you have any questions concerning such matters, please contact any of the following attorneys in our Food, Drug, and Device Practice Group:

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⁸ *Id.* at 61112.

⁹ *Id.*