

What's In The Wash? FDA Rules On Antibacterial Soaps

Law360, New York (January 24, 2014, 7:00 PM ET) -- Makers of consumer antibacterial hand and body washes have promoted their products as a safe and effective alternative to ordinary soap and water for years. Without question this market has grown significantly as consumers seek new ways to protect the health of their families and themselves. But this growth has not come without controversy.

Consumer groups, armed with studies suggesting that these products may not be as safe and effective as advertised, have pushed to place restrictions on the use of certain chemical agents found in consumer antibacterial washes. Much of this focus has been on triclosan and triclocarban, two of the most prevalent active ingredients used in these products. Proffered arguments against these products range from lack of effectiveness to hormone disruption, and the potential for increasing the development of bacterial resistance.

Responding to pressure from these groups, and in particular a lawsuit brought by the Natural Resources Defense Council, the U.S. Food and Drug Administration issued a proposed rule on Dec. 17, 2013, to establish conditions under which over-the-counter consumer antiseptic products intended for use with water are “generally recognized as safe and effective” (“GRAS/GRAE”).[1]

This proposed rule will amend the FDA’s 1994 tentative final monograph (“1994 TFM”), essentially a proposed rule, for OTC antiseptic drug products. In this case, the 1994 TFM was never finalized. According to Debbie Lumpkins, Deputy Director of the Division of Nonprescription Regulation Development at the FDA, the FDA was prompted to reevaluate the tentative conclusions reached in the 1994 TFM because “new scientific developments altered the FDA’s previous safety and effectiveness considerations as to the active ingredients found in OTC antiseptic drug products, one of which is the active ingredient triclosan.”[2]

Comments to the proposed rule are due by June 16, 2014, and companies have until December 2014, to submit new data and information. The FDA has indicated its goal is to have the final rule in place by September 2016.

As discussed below, the FDA’s action has the potential to accelerate lawsuits filed against makers of consumer antibacterial hand and body washes. Therefore, companies that market these products must prepare to not only respond to the FDA but to prepare for a potential increase in litigation as well.

Products Involved

The proposed rule covers only consumer antiseptic washes that are intended for use as either a hand or body wash and does not include health care antiseptics for use in hospitals or in other specific health

care situations. The proposed rule also does not apply to hand sanitizer products; however, it is likely that those products will be the subject of future FDA action as the agency is undertaking a larger, ongoing review of antibacterial active ingredients.[3]

Research, Reformulate or Relabel?

The proposed rule addresses 22 active ingredients, including triclosan and triclocarban, that were classified for OTC antiseptic hand wash use in the 1994 TFM. It is the FDA's position that currently available data do not provide enough support to consider any of these active ingredients as either effective or safe for use in OTC consumer antiseptic wash products.

A summary of the FDA's present position on effectiveness and safety in regard to OTC antiseptic active ingredients, and what will be necessary to support a GRAS/GRAE determination is as follows:

Effectiveness

The FDA takes the position that currently available data are not sufficient to show an additional benefit from the use of consumer antiseptic hand or body washes as compared to using non-antibacterial soap and water. The FDA proposes requiring that the use of any active ingredient in a consumer antiseptic wash product be supported by clinical outcome studies that demonstrate a direct clinical benefit. The FDA defines a clinical benefit as a reduction in the number of infections in the population that uses the antiseptic wash and not just a reduction in observed quantities of bacteria.

Safety

The FDA expressed concerns over data suggesting that systemic exposure to the active ingredients in consumer antiseptic hand or body washes is higher than previously thought and may be linked to a number of effects, including hormonal disruption. The agency also expressed concern that new information suggests that widespread antiseptic use can have an impact on the development of bacterial resistance.

As a response to these concerns, the FDA is proposing that safety data be submitted for each consumer antiseptic wash active ingredient. Three broad categories are proposed for this data: (1) safety-data studies described in current FDA guidance; (2) data to characterize potential hormonal effects; and (3) data to evaluate the development of resistance.

Prior to the finalization of the proposed rule, companies will have to provide the agency with data that meet the above criteria supporting the effectiveness and safety of the active ingredient in their products. If they do not, once the rule is effective they will have to reformulate by removing the antibacterial active ingredient or remove the antibacterial claim from the product's labeling.

Potential Litigation Trends

The sweeping nature of the proposed rule was to be expected. As early as April 2010, the FDA raised questions about the safety of triclosan and stated its position that it did "not have evidence that triclosan in antibacterial soaps and body washes provides any benefit over washing with regular soap and water." [4] Thus, the FDA's current position is not surprising. Even less surprising is the fact that even prior to the issuance of the proposed rule manufacturers of antibacterial soaps were already finding themselves the subject of lawsuits based on fraud and warranty claims in regard to promises of product

efficacy.[5]

Given that the FDA has only allowed manufacturers until December 2014, to submit new data and information, companies will have to act quickly to determine if they have the required data necessary to support a GRAS/GRAE determination. If they are unable to meet the high bar set by the FDA, not only will they be faced with reformulating or relabeling their products, they can also expect increased exposure to potential lawsuits. Even if they do clear the bar set by the FDA, the number of lawsuits regarding efficacy claims will likely rise based on the competing data.

Though personal injury lawsuits are less likely, a cursory Google search reveals that plaintiffs' firms are actively seeking individuals who claim to have sustained injuries they attribute to products containing triclosan. Though triclosan and triclocarban are the two most prevalent active ingredients in consumer antibacterial hand and body washes, any antibacterial that is subject to the proposed rule is also likely to gain increased attention from the plaintiffs' bar.

Environmental claims are also a possibility. One study cited by the FDA identified triclosan as among the top seven organic wastewater contaminants in the survey.[6]

So is this the end of antibacterial hand and body washes? Given the market for such products, the end of this product category is unlikely. Still, manufacturers and their legal counsel must be proactive. Collecting and analyzing the plethora of scientific studies that presently exist is necessary as is conducting new studies or collecting and analyzing studies and data submitted to the FDA.

Importantly, because the present lawsuits pending in the industry are based on product efficacy, companies need to review their advertising materials to ensure that their claims — past, present and future — are supported by sufficient data. Advertising must not overstate the health benefits of the product, including its ability to eliminate disease causing germs or its superiority to washing with regular soap and water. If products are to be reformulated, care will still need to be exercised so that advertising claims match the data supporting any new active ingredients.

Ultimately, though the FDA's actions will likely guide the future of the antibacterial hand and body wash industry, litigation may certainly have a more profound effect on shaping the future of these products.

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[1] Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record, 78 Fed. Reg. 76443 (proposed December 17, 2013).

[2] Declaration of Debbie L. Lumpkins, filed as document 35 in Natural Resources Defense Council, Inc. v. United States Food and Drug Administration, et al., Case No. 1:10-cv-05690 (S.D. N.Y.).

[3] See FDA News Release: FDA issues proposed rule to determine safety and effectiveness of antibacterial soaps (Dec. 17, 2013), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm378542.htm>.

[4] FDA Note to Correspondents: FDA Provides Information to Consumers about the Ingredient Triclosan (April 8, 2010), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm207833.htm>.

[5] See *In re: Colgate-Palmolive Softsoap Antibacterial Hand Soap Marketing and Sales Practices Litigation*, Case No. 1:2012md02320 (D. N.H.); *In re: Dial Complete Marketing and Sales Practices Litigation*, Case No. 1:2011md02263 (D. N.H.).

[6] Dana Kolpin, et al., Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. streams, 1999-2000: a National Reconnaissance, *Environ. Sci. Technol.* 2002, 36, 1202-11.
