Katten
Katten Muchin Rosenman LLP

Regulatory Advisory

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New FDA Regulations for OTC Antibacterial Hand and Body Washes

On September 2, 2016, Food and Drug Administration (FDA) issued a new rule prohibiting the use of certain popular ingredients in over-the-counter (OTC) antiseptic wash products designed to be used with water, such as antibacterial soaps and body washes. The new rule will take effect in approximately one year. FDA also deferred ruling on the use of certain ingredients in these products, to allow for submission of more testing and data. Below are the key highlights and follow-up on FDA's final rule.

What You Need to Know

The FDA's final rule represents a finding that these 19 active ingredients are not generally recognized as safe and effective (GRAS/GRAE) for use in OTC consumer antiseptic wash products and are therefore misbranded in the absence of an approved new drug application. The final rule will prohibit the use of 19 active ingredients in OTC wash products, including the two most commonly used ingredients: triclosan and triclocarban. See below for the full ingredient list.

The new rule will take effect on September 6, 2017, finalizing the FDA's December 2013 proposed rule and amending the 1994 tentative final monograph for OTC antiseptic drug products that was published in June 1994. FDA is deferring its ruling for one year on three other active ingredients: benzalkonium chloride, benzethonium chloride, and chloroxylenol. FDA will accept additional safety and effectiveness data for these ingredients.

The ruling applies to OTC consumer antiseptic wash products, which are intended for use with water and are rinsed off after use (e.g., hand and body washes). In separate rulemakings, FDA is evaluating: (1) OTC consumer antiseptic rubs (products not rinsed off after use, such as hand rubs and antibacterial wipes); and (2) OTC antiseptics intended for use by health care professionals inside or outside of hospitals. Accordingly, these products are not impacted by this final rule, nor are first aid antiseptics or antiseptics used in the food industry.

What You Can Do

- Evaluate your current product line and pipeline for products containing the ingredients listed below, particularly with respect to hand and body washes.
- Assess whether you currently use or have an interest in using the three deferred ingredients in hand or body washes.
- Determine if you need assistance with evaluating your product line, determining applicability of the rules to one or more of your products, or submitting additional safety and effectiveness data on the deferred ingredients to FDA.

For more information, please contact the following Katten attorney.

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- Determine if you have an interest in other ongoing FDA rulemakings regarding OTC consumer antiseptic rubs or antiseptics intended for use by healthcare professionals inside or outside of hospitals.

Resources

- The final rule was published on Tuesday, September 6 and is available here.
- The FDA's news release regarding the final rule is available here.

Full List of Newly Prohibited Ingredients

- Cloflucarban
- Fluorosalan
- Hexachlorophene
- Hexylresorcinol
- Iodophors (iodine-containing ingredients)
  - Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)
  - Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)
  - Nonylphenoxypoly (ethyleneoxy) ethanoliodine
  - 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 amyltricresols
- Sodium oxychlorosene
- Tribromsalan
- Triclocarban
- Triclosan
- Triple dye

Ingredients on Which FDA Has Deferred Action

- Benzalkonium chloride
- Benzethonium chloride
- Chloroxylenol