Health Law Daily Wrap Up, SAFETY AND EFFECTIVENESS—PROPOSED RULES: FDA to require additional data to determine proper use for over-the-counter antiseptic washes, (Dec. 17, 2013)

By Melissa Skinner, JD

The FDA announced the issuance of a final rule to amend a 1994 tentative final monograph or proposed rule (TFM) to establish conditions under which over-the-counter (OTC) consumer antiseptic drug products intended for use with water are generally recognized as safe (GRAS) and are generally recognized as effective (GRAE). Since the issuance of the 1994 TFM, the FDA has discovered that additional data is necessary to make a GRAS/GRAE determination for these products. Written or electronic comments may be submitted by June 16, 2014 (Proposed Rule, 78 FR 76444, December 17, 2013).

Background. The 1994 TFM contained a list of 22 antiseptic active ingredients that were classified for use in OTC antiseptic washes. Of those 22 active ingredients only one, povidone-iodine, was identified as GRAS/GRAE. Some of the 22 active ingredients were determined to be GRAS but not GRAE due to a lack of effectiveness data. The FDA now asserts that none of the 22 active ingredients have the necessary supporting data to be considered either GRAS or GRAE, including povidone-iodine. Triclosan and Triclocarban, both on the list of 22 active ingredients, are two of the most commonly used active ingredients in OTC antiseptic washes and are described by the FDA to be “the subject of much scientific debate.”

Effectiveness. A determination of GRAE is developed using a benefit-to-risk ratio analysis for the specific drug product in question. In light of recent developments, the FDA asserts that new data is needed to show that there is additional benefit in using antibacterial hand and body washes as compared to the use of non-antibacterial soap and water. As such, the FDA proposes the requirement of additional effectiveness data from clinical outcome studies to indicate GRAE for OTC consumer antiseptic washes.

Safety. Similarly, based on the evolution of technology and development of new testing methods since the 1994 TFM, the FDA has acknowledged a need for additional data to support a GRAS determination for the OTC consumer antiseptic washes. Specifically, the FDA proposed rule calls for safety data in three areas: (1) Safety data from FDA guidance; (2) data in regard to the characterization of potential hormonal effects from the use of the drug products; and (3) data regarding the development of resistance to the drug products.

Federal Register Issuances: Proposed Rules Safety News OTC News