
By Bryant Storm, JD

The FDA published a Proposed rule setting out the circumstances under which over-the-counter (OTC) antiseptic products are generally recognized as safe and effective (GRAS/GRAE) for use by health care professionals in or out of a hospital setting. The Proposed rule is intended to amend the 1994 tentative final monograph or Proposed rule for OTC antiseptic drug products (59 FR 31402, June 17, 1994). In light of scientific developments since the 1994 Proposed rule was published, the FDA is proposing additional data requirements to support the safety of antiseptic active ingredients. Only “health care antiseptics” used by health care professionals are covered by the Proposed rule. The covered products include personnel hand washes, health care personnel hand rubs, surgical hand scrubs, surgical hand rubs, and patient preoperative skin preparations (Notice, 80 FR 25166, May 1, 2014).

**Safety and effectiveness.** The determination of whether an active ingredient would be GRAS/GRAE for a particular use requires consideration of a benefit-to-risk ratio. The approach for conducting such a benefit and risk analysis has been altered by the FDA as a result of 2005 meeting of the Nonprescription Drugs Advisory Committee (NDAC) and new analytical techniques, which can detect active ingredients in bloodstream and tissue at much lower levels are now available. Since 1994, new information has also emerged regarding risks from systemic absorption and long-term exposure to antiseptics. The impact of antiseptics on the growing problem of antibacterial resistance is an additional safety consideration that has recently emerged. As a result, the “standard battery of tests” used to determine the safety and effectiveness of antiseptics has advanced significantly.

**Data.** The data sought by the Proposed rule is classified into four categories: (1) Human safety studies; (2) nonclinical safety studies; (3) data to characterize potential hormonal effects; and (4) data to evaluate the development of antimicrobial resistance. The specific kinds of additional safety data that the proposal would require includes “in vitro data characterizing the ingredient’s antimicrobial properties and in vivo clinical simulation studies showing that specified log reductions in the amount of certain bacteria are achieved using the ingredient.” Although the FDA thinks that some manufacturers may already have this additional data to prove whether an active ingredient is GRAS/GRAE, “to date these data have not been submitted to the OTC Drug Review.”

Due to the complexity of the Proposed rule, the agency is accepting comments for a 180-day period, through October 28, 2015.