

Antiseptic meetings

Consumer hand and body wash antiseptics

March 20, 2015: A meeting with American Cleaning Institute to discuss the safety and effectiveness data gaps for the active ingredients benzethonium and benzalkonium chloride and propose a new and significant set of testing requirements to fill those gaps and establish that those active ingredients are generally recognized as safe and effective when used in consumer antiseptic products intended for use with water.

- [Meeting background package](#)
- [Letter Granting Meeting Request](#)
- [Meeting minutes](#)
- [Advice letter](#)

April 24, 2015: A meeting with American Cleaning Institute to discuss the safety and effectiveness data gaps for the active ingredient chloroxylenol and propose a new and significant set of testing requirements to fill those gaps and establish that those active ingredients are generally recognized as safe and effective when used in consumer antiseptic products intended for use with water.

- [Meeting background package](#)
- [Letter Granting Meeting Request](#)
- [Meeting minutes](#)

May 6, 2015: A meeting with Lonza America, Inc. to discuss overall approach for providing a safety database for the active ingredients benzethonium and benzalkonium chloride in consumer antiseptic hand washes.

- [Meeting background package](#)
- [Letter Granting Meeting Request](#)
- [Meeting minutes](#)
- [Advice letter](#)

May 25, 2016: A meeting with Lonza America, Inc. to obtain clarification on the human pharmacokinetic maximal use trial (MUsT) and discuss the process of requesting a time extension for completion of the MUsT and other safety data required to support generally recognized as safe listing for benzethonium chloride and benzalkonium chloride.

- [Meeting background package](#)
- [Letter Granting Meeting Request](#)
- [Meeting minutes](#)

Health care antiseptics

July 30, 2015: A meeting with GOJO Industries, Inc. to discuss the protocols submitted to health care antiseptic Docket No. FDA-2015-N-0101 regarding Physiologically-Based Pharmacokinetic (PBPK) Modeling, formulation variances, and efficacy for ethyl alcohol.

- [Meeting background package](#)
- [Letter Granting Meeting Request](#)
- [Meeting minutes](#)

October 20, 2015: A meeting with American Chemistry Council to discuss the data gaps identified for isopropyl alcohol for use in patient preoperative skin preparations, healthcare personnel hand rubs, and surgical hand rubs.

- [Meeting background package](#)
- [Letter Granting Meeting Request](#)
- [Meeting minutes](#)

May 25, 2016: A meeting with Lonza America, Inc. to obtain clarification on the human pharmacokinetic maximal use trial (MUsT) and discuss the process of requesting a time extension for completion of the MUsT and other safety data required to support generally recognized as safe listing for benzethonium chloride and benzalkonium chloride.

- [Meeting background package](#)
- [Letter Granting Meeting Request](#)
- [Meeting minutes](#)

June ---, 2016: A written response to American Chemistry Council as follow-up to the October 20, 2015 meeting and in response to FDA's meeting minutes to further discuss the data gaps identified for isopropyl alcohol for use as in patient preoperative skin preparations, healthcare personnel hand rub, and surgical hand rubs.

- [Meeting background package](#)
- [Letter denying Meeting Request](#)
- [Advice letter](#)