FDA Holds Public Meeting on Cosmetic Microbiological Safety Issues to Consider Need for New Guidelines

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On November 30, 2011, the Food and Drug Administration (FDA) held a public meeting to consider the need to amend pre-existing guidelines or adopt new ones addressing microbiological safety in cosmetics. The FDA presented the meeting as an opportunity for industry and other stakeholders to provide input on whether current guidelines sufficed to address cosmetic microbiological safety.

The FDA and industry members have long acknowledged the capacity for microorganisms to grow and reproduce in cosmetics if certain precautions are not taken. This growth can cause chemical changes to the products, which may adversely affect the consumer. In explaining the impetus behind the meeting, FDA representatives noted that current FDA guidelines on microbiological safety have not been revised in some time. These guidelines include the Cosmetic Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist (2008) and the Bacteriological Analytical Manual (BAM), Chapter 23 “Microbiological Methods for Cosmetics” (2001). FDA representatives stated that they were in the process of revising these guidelines and also considering issuing entirely new guidelines on microbiological safety.

Industry members indicated a willingness to collaborate on any revised or new guidelines, but noted that current industry practice already ensured the safety of cosmetics. Dr. Jay Ansel of the Personal Care Products Council, which represents more than 600 companies manufacturing personal care products, referred to studies finding an incident report of one per every 270 million units sold. Phil Geis of Geis Microbiological Quality cited industry practice of monitoring product safety from start to finish of the product cycle as the reason for the low incident rate. Geis also argued that requiring complete sterility in all products would be unnecessarily expensive and stifle innovation for no discernible benefit.

Despite industry assurances of safety, FDA representatives responded that they were interested in taking a “preventative approach” to cosmetic microbiological safety and suggested this could be effectuated by updating and aligning various sources of information on microbiological safety.

It is important to note that the only action contemplated by the meeting was the issuance of nonbinding guidelines. Unlike its authority over drugs and medical devices, the FDA lacks authority to require pre-market approval of cosmetics. The FDA can only take action against a specific cosmetic product once it has been found to be adulterated or misbranded and therefore it cannot require cosmetic companies to comply with guidelines on cosmetic microbiological safety prospectively.

The FDA urged interested parties to submit written comments to the docket by January 30, 2012. More information, along with the link to submit comments to the docket, is available here.

This blog post was written by Donnelly McDowell.