On October 24, FDA released a revised draft guidance document titled “Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers.” This draft guidance supersedes the 2014 draft guidance “Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices.”

The draft guidance pertains to approved/cleared medical products, including certain medical devices, human drugs, and animal drugs. The revised guidance provides information relating to firms, i.e., “persons legally responsible for the labeling of medical products,” communicating about scientific information on unapproved uses (SIUU) to healthcare providers. SIUU communications must be truthful and non-misleading, and FDA proposes not to use communications consistent with the guidance alone as evidence of a new intended use requiring premarket authorization.

The draft guidance answers questions about appropriate source publications, necessary information, presentation considerations, and other general recommendations for SIUU. Source publications should be scientifically sound and clinically relevant. In addition to being truthful and non-misleading, SIUU should “provide all information necessary for HCPs to interpret the strengths and weaknesses and validity and utility” of the information. The communications should be...
clear, objective, distinct from promotional language about approved use, and shared on appropriate media.

- FDA is also seeking comments on two specific questions related to the guidance regarding considerations unique to communications of SIUU to researchers and any other factors firms should consider when sharing presentations to healthcare providers.
- FDA is accepting comments until December 26, 2023. Keller and Heckman will continue to monitor developments in this area.

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Source URL: https://www.natlawreview.com/article/fda-seeks-comments-revised-draft-guidance-communicating-scientific-information