KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

January 7, 2013

FDA Announces Public Meeting to Discuss Standardization and Availability of Medical Device Labeling

On April 29-30, 2013, FDA will hold a public workshop to discuss standardizing the format and content of medical device labeling and the development of a public repository/database that would provide access to the labeling of certain medical devices. In its announcement of the meeting, FDA stated it is concerned that lack of standardized content and format and access to medical device labeling may increase the risk of medical errors. Standardization and public access to medical device labeling raises several potential regulatory concerns (*e.g.*, the ability to make modifications to the labeling) and could have product liability implications. Therefore, we recommend that clients closely follow FDA's proposals and developments on this issue and consider submitting comments.

The meeting will be held at FDA's White Oak campus in Silver Spring, MD and will also be webcast. All attendees are required to register by April 5, 2013. Registration can be accessed through FDA's Medical Devices News & Events - Workshops & Conferences calendar available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshipsConferences/default.htm. Early registration is recommended due to the limited space and webcast connections. On-site registration will be offered the day of the meeting if time and space allow. As part of the registration process, interested persons may request to make oral presentations during the public comment period of the meeting. Requests for oral presentations must be received by April 5, 2013, 5:00 pm EST.

The Agency is seeking input and comment on the following high-level topics that will be discussed at the meeting: (1) Summary of FDA Work on Labeling, (2) Standard Content and Format of Device Labeling, and (3) Repository of Medical Device Labeling for Home Use Devices. A more detailed list of topics can be found in the Federal Register notice announcing the meeting (FR Doc. 2013-00003 Filed 01/04/2013). FDA is also soliciting comments from stakeholders on all aspects of the workshop topics regardless of attendance at the meeting. Comments may be submitted electronically through http://www.regulations.gov or in writing to the Division of Dockets Management (HFA-305), Food and Drug Administrations 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Reference to Docket Number FDA-2012-N-1205 should be included with submitted comments.

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King & Spalding is happy to assist clients with preparation of comments and to discuss other aspects of the upcoming meeting. We will be following this issue closely and will provide an update on any significant developments.