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Medical Device Update: FDA Medical Device Guidances Issued in 2014's Second Quarter

In recent months, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) has issued draft and final guidance documents at a relatively fast pace. To assist interested parties, we have analyzed some of the more significant guidances that were issued in the second quarter of 2014 (April–June). Provided below are brief summaries of several guidance documents that affect manufacturers and marketers of medical devices.

Global Unique Device Identification Database (GUDID), Guidance for Industry and Food and Drug Administration Staff (June 27)

The FDA published a final rule on the Unique Device Identification (UDI) System on September 24, 2013 and issued a draft guidance document on the same date. Recently, the FDA issued its "Global Unique Device Identification Database (GUDID): Guidance for Industry and Food and Drug Administration Staff," which finalizes the draft guidance document and supersedes the guidance version that was issued on June 11, 2014.

The guidance provides information on how to establish and use a GUDID account, how to create and maintain a unique device identifier, and other key GUDID concepts. Additionally, information is provided on electronic records and electronic signatures. The first deadline for compliance with the UDI requirements is September 24, 2014, and it applies to Class 3 devices and devices licensed under the Public Health Service Act. The FDA encourages labelers of these devices to establish accounts and begin submitting data to the GUDID. Those who require assistance should contact the FDA's UDI Help Desk.[1]

Draft Guidance Documents on Using Internet/Social Media Platforms (June 18)

On June 18, the FDA issued two draft guidance documents related to using social media to promote medical devices and prescription drugs—one on using social media platforms with character space limitations[2] and one on correcting misinformation on third-party social media platforms.[3] Comments on the two draft guidances may be submitted for the FDA's consideration through September 16, 2014.

The draft guidance on character space limitations is intended to address online microblog messaging, such as messages on Twitter (i.e., "tweets"), which are limited to 140 character spaces per tweet, and online paid searches (e.g., "sponsored links" on search engines, such as Google and Yahoo), which also have limited character spaces. The draft guidance states that the FDA's policy is that, if a firm is making product benefit claims, it also should incorporate risk information, regardless of character space constraints. For example, the FDA states that an appropriate promotional tweet would be "NoFocus for mild to moderate memory loss; may cause seizures in patients with a seizure disorder www.nofocus.com/risk." Given the challenges presented by the draft guidance recommendations, the FDA advises that firms "carefully consider the complexity of the indication and risk profiles" for a product to determine whether using messages such as tweets is an appropriate or viable promotional tool for a particular product.

The FDA's draft guidance on correcting independent third-party misinformation sets forth guidelines for how medical device firms should respond, if they choose, to misinformation regarding their own FDA-approved or

1. The Help Desk can be contacted at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.

2. Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices, *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf.

3. Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices, *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf.

FDA-cleared products when the misinformation is disseminated by independent third parties on the Internet or through social media. This could include, for example, misinformation on a third party's blog or a third-party discussion site. The draft guidance provides that medical device firms can respond to correct the information, without providing risk information, provided that the corrective information is accurate, nonpromotional in nature, and relevant, responsive, and limited to the misinformation. The draft guidance further recommends that FDA-required labeling be included or be provided in a readily accessible format. Several approaches to correcting misinformation are provided.

Providing Information about Pediatric Uses of Medical Devices, Guidance for Industry and Food and Drug Administration Staff (May 1)

The Food and Drug Administration Amendments Act of 2007 requires entities that submit premarket approval applications, humanitarian device exemptions, and product development protocols for new devices to include readily available information about pediatric subpopulations that suffer from a disease or condition that the device is intended to treat, diagnose, or cure.[4] This final guidance[5] describes the type and scope of information required by the statute.

Specifically, the guidance describes the following:

- The types of premarket submissions subject to the requirement to include pediatric information
- The type of information that must be included
- What is meant by "readily available" information
- Definitions of the "pediatric patient population" and "pediatric subpopulations"
- Acceptable sources of 515A pediatric information
- Where to include pediatric information in a submission
- How the FDA intends to use the submitted pediatric information

The FDA clarifies that submitting the required information is not considered sufficient to establish the safety and effectiveness of a device for a new pediatric indication and that additional data generally would be required.

Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials, Draft Guidance for Institutional Review Boards, Industry, Investigators, and Food and Drug Administration Staff (April 17)

It has become increasingly common for sponsors to provide live case presentations during clinical investigations of investigational devices used in complex surgical procedures in order to communicate information efficiently to investigators and potential investigators. On April 17, CDRH issued draft guidance[6] to clarify the FDA's regulations and policies because of its concerns related to human subject protection and uncertainty about potential differences among the outcomes of subjects participating in live case presentations. The aim of the guidance is to encourage sponsors to submit the information on live case presentations that is required for FDA review, as described in the guidance, at the time of an IDE submission or 30 days prior to the planned presentation. The FDA's view is that the purpose of a live case presentation is to increase awareness of the study for potential investigators and facilitate recruitment of subjects, and, accordingly, a live case presentation request is not appropriate for a study nearing completion.

4. Federal Food, Drug, and Cosmetic Act § 515A, 21 U.S.C. § 360e-1.

5. View the final guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM339465.pdf.

6. View the draft guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393107.pdf.

Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions, Draft Guidance for Industry and Food and Drug Administration Staff (April 23)

The FDA announced in April 2014 a new expedited access program for Class 3 medical devices that address unmet medical needs.[7] The Expedited Access PMA (EAP) program contains features of the Innovation Pathway and parallels expedited programs available for drugs and biologics. The EAP program features interactive review, senior management involvement, a case manager, and priority review of the marketing application. Eligibility for the program includes (1) an intention to treat or diagnose a life-threatening or irreversibly debilitating disease or condition, (2) addressing an unmet need by providing a clinically meaningful advantage over existing technology or where there is no approved alternative or where it is in the best interest of patients, and (3) submission of an acceptable Data Development Plan, which describes the clinical and nonclinical data that would be collected premarket and postmarket.

Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval, Draft Guidance for Industry and Food and Drug Administration Staff (April 23)

CDRH has identified striking the right balance between premarket and postmarket data requirements to facilitate device development and review as one of its three strategic priorities for 2014. In April 2014, it issued draft guidance that outlines the role of postmarket information in supporting premarket approval.[8] Some of the examples given by CDRH to illustrate when it may be appropriate to rely on postapproval studies include (1) mature technology, (2) confirmation of mitigation effectiveness for a known risk. (3) data collection for specific or rare adverse events, (4) approval for an intended population beyond what was fully evaluated in the pivotal trial, (5) assessment of long-term performance in a postapproval study, and (6) confirmation of bench data with clinical data. The guidance also states that the FDA may impose postmarket requirements at the time of approval as a condition of approval.

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, Guidance for Industry and FDA Staff (May 13)

The FDA issued draft guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices." Once finalized, this guidance will replace and supersede the existing "Guidance for Industry and FDA Staff; Recognition and Use of Consensus Standards" from September 17, 2007. Comments on the draft guidance[9] are due by August 11, 2014.

Consensus standards are used by the FDA and industry for various purposes, including to facilitate the premarket review process. For example, submitters of premarket submissions may not be required to include their underlying test data showing conformity with a standard if they file a declaration of conformity. The draft guidance proposes two changes in policy with respect to using consensus standards:

- Declarations of conformity should no longer be used when the submitter deviates from an FDA-recognized standard. Rather, the submitter must certify that its device conforms to all of the requirements of an FDA-recognized consensus standard (except when a requirement is not applicable).
- Promissory statements that indicate future conformance with a consensus standard (i.e., prior to marketing) are not appropriate to support a premarket submission.

Additionally, although not described as a change in policy, the draft guidance states that a declaration of conformity will not allow submitters to avoid submitting the underlying data in all cases. For some FDA-recognized consensus standards that are general and broad in scope, the FDA may find that it cannot determine whether the standard has been met without the underlying data.

7. View the guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf.

8. View the guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393994.pdf.

9. View the draft guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM396568.pdf.

Types of Communication During the Review of Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff (April 4)

This guidance[10] finalizes the draft guidance, which was issued on April 5, 2013. As part of its commitment to improve the device review process and increase its transparency, the FDA has agreed to new communication commitments in its Medical Device User Fee Amendments of 2012 (MDUFA III) Commitment Letter. This guidance describes how that commitment will be met for four types of communication that occur during the review of a medical device submission: (1) acceptable review communications for 510(k)s, original premarket approval applications (PMAs), panel track PMA supplements, and presubmissions; (2) substantive interactions for 510(k)s, original PMAs, panel track PMA supplements, and 180-day PMA supplements; (3) interactive review; and (4) missed MDUFA decision communication for 510(k)s, original PMAs, and panel track PMA supplements.

Pursuant to the guidance, the FDA will issue acceptance review communications within 15 days of receiving a 510(k), original PMA, or panel track PMA supplement and within 14 days of receiving a presubmission. A substantive interaction should occur within 60 days of receiving a complete 510(k), 90 days of the filing date for an original PMA or panel track PMA supplement, and 90 days of the receipt date for a 180-day PMA supplement. For interactive review communications, the FDA intends to engage in these types of communications after a substantive review. Finally, the FDA should issue a missed MDUFA decision communication for those submissions that have not reached a MDUFA decision by 100 FDA days for 510(k)s and 20 FDA days after the applicable FDA goal for original PMAs and panel track PMA supplements. The FDA's guidance also addresses the appropriate purpose and content of each of the four types of communications.

Contacts

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10. View the guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM341948.pdf.