

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sharon Lappalainen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1238, Silver Spring, MD 20993-0002, 301-796-6322.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance describes a means by which electrocardiograph electrodes may comply with the requirement of special controls for class II devices. In the **Federal Register** of October 4, 2007 (72 FR 56771), and Docket No. FDA-2007D-0309, FDA proposed to classify electrocardiograph electrodes, intended to acquire and transmit the electrical signal at the body surface to a processor that produces an electrocardiogram (ECG) or vectorcardiogram, into class II. FDA also proposed to exempt this device from premarket notification requirements and issued a draft guidance document to describe the special control requirements. FDA invited interested persons to comment on the proposed regulation and the draft guidance document by January 8, 2008. FDA received seven comments on the proposed rule. These comments addressed issues pertaining to labeling, the scope of the devices subject to the classification rule, and testing. In response, FDA has revised the labeling section of the guidance, has clarified the scope of the guidance, and has clarified the information regarding testing for shelf life. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify electrocardiograph electrodes into class II (special controls) and to exempt the device from 510(k) premarket notification procedures.

II. Significance of Special Controls Guidance Document

FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of electrocardiograph electrodes classified under § 870.2360 (21 CFR 870.2360). In order to be classified as a class II device under § 870.2360, an electrocardiograph electrode must comply with the requirements of special controls; manufacturers must address the issues requiring special controls as identified in the guidance document, either by

following the recommendations in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>.

To receive "Class II Special Controls Guidance Document: Electrocardiograph Electrodes," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a paper copy. Please use the document number (#1597) to identify the guidance you are requesting.

IV. Paperwork Reduction Act

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0130; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 18, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0495]

Unique Device Identification for Postmarket Surveillance and Enforcement; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop on the adoption, implementation, and use of unique device identifiers (UDIs) in various health-related electronic data systems. The purpose of this workshop is to engage multiple stakeholders to obtain information and comments on issues confronting the effective and efficient incorporation of UDIs into appropriate data sets, to identify barriers and incentives to their adoption and use, and to understand the best solutions and practices to resolve open issues.

Dates and Times: The public workshop will be held on September 12, 2011, from 1 to 5 p.m. and on September 13, 2011, from 9 a.m. to 5 p.m. Submit electronic and written comments by October 13, 2011.

Location: The public workshop will be held at the Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Road, Bethesda, MD 20852; 301-822-9200.

Contact Person: Jay Crowley, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301-980-1936, e-mail: jay.crowley@fda.hhs.gov

Registration: Registration is free and will be on a first-come, first-served basis. To register for the public workshop—whether attending in person or for the Web cast—please visit <http://www.fda.gov/UDI> (or go the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, e-mail, and telephone number. For those without Internet access, please contact Jay Crowley (see Contact Person) to register. Registration requests should be received by 5 p.m. on September 5, 2011. Early registration is recommended because seating is limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the

day of the public workshop will be provided beginning at 11 a.m.

Hotel reservations can be made by calling the hotel and requesting the group rate for the "FDA UDI Public Workshop" room block.

If you need special accommodations due to a disability, please contact Jay Crowley (jay.crowley@fda.hhs.gov) at least 7 days in advance.

The meeting will also be Web cast. Persons interested in participating by Web cast must register online by 5 p.m. on September 5, 2011. Web cast participants will be sent connection requirements. More information on the Web cast can be found on our Web site at <http://www.fda.gov/UDI>.

By August 12, 2011, and then as available, FDA will post the workshop agenda and discussion topics, registration information, information about lodging, and other relevant information on the Internet at <http://www.fda.gov/UDI>.

Comments: Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments by October 13, 2011. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) directs FDA to issue regulations establishing a UDI system for medical devices. FDA is developing proposed regulations to establish this UDI system to strengthen and improve FDA's enforcement of other statutory authorities and improve the identification of devices through distribution and use. This workshop will not address the FDA's UDI regulatory framework. However, UDI systems have been under development for some years by the U.S. and global device industry and some device manufacturers have been incorporating UDI into their product labeling and packaging. See <http://www.fda.gov/UDI> for more information about UDI.

FDA is also leading an effort to develop and implement a national

strategy for the best public health use of health-related electronic data related to devices that incorporates UDIs, including registries, and leverages existing processes and systems. Health-related data (from large data sources such as health insurers and integrated health systems, and others) contains a wealth of public health information that could be harnessed to contribute to understanding device safety and effectiveness. Currently, however, these data generally cannot be used to identify specific device exposures in patients. This is not the case for drug exposure, where the regular documentation of NDC numbers allows for robust analysis of pharmaceutical safety and effectiveness. Absent such information for devices, a vast amount of potentially useful data regarding patient safety and outcomes remains untapped.

The incorporation of UDI into various health-related databases will greatly facilitate many important public health-related activities including:

- Reducing medical errors,
- Reporting and assessing device-related adverse events and product problems,
- Tracking of recalls,
- Assessing patient-centered outcomes and the risk/benefit profile of medical devices in large segments of the U.S. population,
- Providing an easily accessible source of device identification information to patients and health care professionals.

The incorporation of UDI into various health-related databases would also greatly expand Sentinel Initiative capabilities to conduct active device surveillance given that Sentinel device data sources are currently limited to a few registries capturing short-term patient outcomes. FDA's Sentinel Initiative, on the Internet at <http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm>, seeks to establish "a national electronic system that will transform FDA's ability to track the safety of drugs, biologics, medical devices—and ultimately all FDA-regulated products once they reach the market" and "aims to develop and implement a proactive system that will complement existing systems that the Agency has in place to track reports of adverse events linked to the use of its regulated products." (Please note that this workshop will NOT address FDA's oversight of EHRs.)

II. Topics for Discussion at the Public Workshop

This public workshop is intended to engage multiple stakeholders to inform FDA's efforts to promote and facilitate

incorporation of UDIs into healthcare systems, obtain actionable information on the issues surrounding effective and efficient incorporation of UDIs into health-related electronic records, and understand best solutions and practices. To that end, we will focus on the following issues:

A. Documenting Device Use Using UDIs in Electronic Health Records

1. The current state of documentation of device use in health-related databases, including EHRs.

2. The barriers to, and various possible incentives for, the development, implementation and use of UDI in EHR systems.

3. The possible roles and activities of various government stakeholders (including FDA, CMS, ONC, and NLM) necessary to drive the adoption and use of UDIs in EHRs and other health-related databases.

4. Any other issues or concerns that would affect the efficient and effective incorporation of UDIs in EHRs and other health-related data.

B. The Role of UDI in Device Registries

5. The current state of documentation of device use in registries.

6. The future vision for device registries using UDI.

7. How EHRs and other, similar population-based databases can be used to provide registries or registry-like data.

8. Any technical issues confronting the effective and efficient incorporation of UDIs into appropriate data sets.

C. UDI's Role in National and Local Data Standards

9. The current state of Health IT data standards in EHRs.

10. The future vision for use of standards in EHRs to improve data quality and data exchange.

11. The activities of the Health IT Standards Panel and its relationship to Meaningful Use.

12. The relationship of data standards to UDI integration in hospital systems.

D. Integrating UDI Throughout Hospital Systems

13. The particular issues associated with networked devices that need to be considered.

14. The issues and challenges with device interoperability.

15. The current and future state of MMIS and RTLS systems to support safe device use.

16. How other information systems are adopting and implementing UDI and how these systems are integrating with other clinical information systems to transmit the appropriate data.

E. The Role of UDI in Postmarket Surveillance and Compliance

17. How we can use UDIs in health-related electronic data systems to improve post-approval studies.

18. How the documentation of UDIs can be used to improve the conduct of recalls.

19. The issues associated with the use of UDI in claims data sources.

20. How adverse event reporting can be improved.

21. Other postmarket surveillance and enforcement activities that can be improved through the documentation of UDIs in these databases.

F. UDIs in Personal Health Records

22. The device information currently being transmitted from the EHR to a patient's PHR.

23. Any lessons learned that can be applied from documenting medication use.

24. How the documentation of UDI in patients' PHRs can be used for postmarket surveillance, enforcement activities and to improve device use.

25. Any differences in documentation and tracking of device use needed for different care settings (e.g., hospital, outpatient clinic, and home) and different device types (e.g., implants, home/patient use) that need to be considered.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857. A link to the transcripts will also be available on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm257194.htm> (or go to <http://www.fda.gov> and select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated: July 15, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0477]

Standard Operating Procedure for "Notice to Industry" Letters

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the standard operating procedure (SOP) for "Notice to Industry" Letters. The SOP describes the Center for Devices and Radiological Health's (CDRH) process to clarify and more quickly inform stakeholders when CDRH has changed its expectations relating to, or otherwise has new scientific information that could affect, data submitted as part of an Investigational Device Exemption (IDE) or premarket submission that needs to be disseminated in a timely manner.

DATES: The Agency encourages interested parties to submit information and either electronic or written comments by September 19, 2011.

ADDRESSES: Submit electronic comments or information to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Angela Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1666, Silver Spring, MD 20993, 301-796-6380, e-mail: angela.krueger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Task Force on the Utilization of Science in Regulatory Decision Making (the Task Force) published a Preliminary Report and Recommendations in August 2010. In the report, the Task Force noted that when new scientific information changes CDRH's regulatory thinking, it has been challenging for the Center to communicate the change and its basis to all affected parties in a meaningful and timely manner. The Task Force recommended that the Center make use of more rapid tools for broad communication on regulatory matters, including establishing a standard practice for sending "Notice to Industry" Letters to all manufacturers of a particular group of devices for which

the Center has changed its expectations for data submitted as part of an IDE or premarket application on the basis of new scientific information.

Currently, manufacturers typically learn of changes CDRH implements at the time of or soon after a decision is made through individual engagement with the Center, often not until after they have prepared a premarket submission. Reviewers may implement these changes, such as requesting new clinical data or using a new test method, on a case by case basis, with immediate supervisory concurrence when it is necessary to protect the public health. For example, a reviewer may request that sponsors test their implantable device for durability because new data demonstrates that this type of device is prone to failure due to premature wear and tear of the technology. Although CDRH may issue a detailed guidance document, the document may not be published until a year or more after a branch- or division-level decision has been made to request the information because of the resource constraints in developing guidance documents.

Therefore, CDRH believes that timely communication with industry about changes in regulatory expectations or new scientific information is important. The Task Force recommended that CDRH use "Notice to Industry" Letters in these circumstances, although not required, and adopt a uniform template and terminology for such letters, including clear and consistent language to indicate that the Center has changed its regulatory expectations, the general nature of the change, and the rationale for the change. The Task Force contemplated that CDRH could potentially issue "Notice to Industry" Letters, if such letters constitute guidance, as "Level 1—Immediately in Effect" guidance documents under 21 CFR 10.115(g)(2), and would open a public docket upon their issuance through a notice of availability in the **Federal Register**.

This SOP was developed to address this recommendation from the Task Force. Where appropriate, CDRH will communicate new expectations as "Notice to Industry" Guidance Letters, which will comply with Good Guidance Practices, or CDRH will communicate other new scientific information as "Notice to Industry" Advisory Letters. The Center will post both types of "Notice to Industry" Letters on its Web site, and will also use additional methods for distributing the Letters to identified stakeholders. When CDRH issues a "Notice to Industry" Guidance Letter concerning a change in premarket expectations that will affect pending