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.

[FR Doc. 2011–18369 Filed 7–20–11; 8:45 am]

BILLING CODE 4160–01–P

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

submissions, the Center will generally specify an additional amount of time for sponsors of those submissions to address the new issues. Where appropriate, ''Notice to Industry'' Guidance Letters would be followed as quickly as possible by new or revised guidance explaining the Center's new regulatory expectations (if any) in greater detail and revising the guidance where necessary in response to comments received, so that external constituencies have a fuller understanding of the Center's current regulatory thinking.

II. Submission of 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 15, 2011.

Nancy K. Stade,

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

[FR Doc. 2011–18387 Filed 7–20–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Cystic Fibrosis, Lung Fibrosis, and Lung Innate Immunity Applications.

Date: August 8, 2011.

Time: 9 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Everett E Sinnett, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301–435–1016, *sinnett@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 14, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–18420 Filed 7–20–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuroimaging.

Date: August 9, 2011.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call)

Contact Person: Eduardo A Montalvo, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1168, *montalve@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Special Emphasis Panel.

Date: August 23, 2011.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call)

Contact Person: Rass M Shayiq, PhD, Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435–2359, *shayiqr@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 15, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–18418 Filed 7–20–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases Diabetes Mellitus Interagency Coordinating Committee; Notice of Meeting

The Diabetes Mellitus Interagency Coordinating Committee (DMICC) will hold a meeting on August 1, 2011, from 8:30 a.m. to 11:30 p.m. at the Bethesda Marriott Suites, 6711 Democracy Blvd, Bethesda, MD 20817. The meeting is open to the public but attendance is limited to space available. Non-Federal individuals planning to attend the meeting should notify the Contact Person listed on this notice at least 2 days prior to the meeting. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below at least 10 days in advance of the meeting.

The DMICC facilitates cooperation, communication, and collaboration on diabetes among government entities. DMICC meetings, held several times a year, provide an opportunity for members to learn about and discuss current and future diabetes programs in DMICC member organizations and to identify opportunities for collaboration. The August 1, 2011, DMICC meeting will discuss ''Guides and Guidelines.''

Any member of the public interested in presenting oral comments to the Committee should notify the Contact Person listed on this notice at least 10