

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR Section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
107.230; Elements of infant formula recall	2	1	2	50	100
107.260; Revision of an infant formula recall	1	1	1	25	25
Total					125

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 reports FDA’s third-party disclosure burden estimates for §§ 107.230 and 107.260. The estimated burden hours per disclosure is an average based on FDA’s experience. The third-party disclosure burden in § 107.230 is the requirement to promptly notify each affected direct-account (customer) about the recall, and if the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post a notice of the recall at the point of purchase. FDA estimates that 2 respondents will conduct infant formula recalls under § 107.230 and that it will take a respondent 50 hours to comply with the third-party disclosure requirements of that section, for a total of 100 hours. The third-party disclosure burden in § 107.260 is the requirement to issue additional notifications where the recall strategy or implementation is determined to be deficient. FDA estimates that 1 respondent will issue additional notifications under § 107.260 and that it will take a respondent 25 hours to comply with the third-party disclosure requirements of that section, for a total of 25 hours.

Dated: August 1, 2014.

Peter Lurie,
Associate Commissioner for Policy and Planning.

[FR Doc. 2014–18665 Filed 8–6–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0383]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Radioactive Drug Research Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Radioactive Drug Research Committees” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On May 9, 2014, the Agency submitted a proposed collection of information entitled “Radioactive Drug Research Committees” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0053. The approval expires on July 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: July 31, 2014.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2014–18609 Filed 8–6–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1088]

Center for Devices and Radiological Health: Experiential Learning Program; General Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for

Devices and Radiological Health (CDRH or Center) is announcing a new component of the Experiential Learning Program (ELP) identified as the ELP General Training Program. This training component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. The purpose of this document is to invite medical device industry, academia, and health care facilities to apply to participate in this formal training program for FDA’s medical device review staff, or to contact CDRH for more information regarding the ELP General Training Program.

DATES: Submit either an electronic or written request for participation in the ELP General Training Program by September 8, 2014.

ADDRESSES: Submit either electronic requests to <http://www.regulations.gov> or written requests to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify proposals with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Latonya Powell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4448, Silver Spring, MD 20993–0002, 301–796–6965, FAX: 301–827–3079, *Latonya.powell@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for ensuring the safety and effectiveness of medical devices marketed in the United States. Furthermore, CDRH assures that patients and providers have timely and continued access to high-quality, safe, and effective medical devices and safe radiation-emitting products. In support of this mission, the Center launched various training and development initiatives to enhance performance of its staff involved in regulatory review and

in the premarket review process. One of these initiatives, the ELP Pilot, was launched in 2012 and fully implemented on April 2, 2013 (see 78 FR 19711).

CDRH is committed to advancing regulatory science; providing industry with predictable, consistent, transparent, and efficient regulatory pathways; and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP General Training Program component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges

faced in broader disciplines that impact the device development life cycle. This component is a collaborative effort to enhance communication and facilitate the premarket review process.

Furthermore, CDRH is committed to understanding current industry practices, innovative technologies, regulatory impacts, and regulatory needs.

These formal training visits are not a mechanism for FDA to inspect, assess, judge, or perform a regulatory function (e.g., compliance inspection), but rather they are an opportunity to provide CDRH review staff a better understanding of the products they

review. Through this notice, CDRH is formally requesting participation from companies, academia, and clinical facilities, including those that have previously participated in the ELP or other FDA site visit programs.

II. ELP General Training Program

A. ELP General Training Component

In this training program, groups of CDRH staff will observe operations at research, manufacturing, academia, and health care facilities. The focus areas and specific areas of interest for visits may include the following:

TABLE 1—AREAS OF INTEREST: OFFICE OF DEVICE EVALUATION

Focus area	Specific areas of interest
Biocompatibility testing	Decisionmaking process for biocompatibility test selection; considerations for use of animal testing vs. in vitro testing; sample preparation of nanoscale, bioabsorbable, and in situ polymerized materials; evaluation of color additives.
Combination products	Devices coated with drug(s); drug delivery products.
Emerging manufacturing methods	3-D printing; additive manufacturing; additional or unique validation and verification activities.
Management of clinical trials for medical devices	Understanding clinical trial infrastructure, roles, responsibilities, and relationships with other organizations involved in the management and conduct of clinical trials; challenges encountered in obtaining regulatory approval and successfully executing a clinical trial; issues related to early feasibility studies; institutional review boards; clinical research organizations.
Reprocessing and sterilization	Reprocessing challenges in the manufacturing or clinical environment; validation of reprocessing or sterilization instructions; simulated use testing; unique sterilization methods (e.g., use of flexible bags, sound waves, ultraviolet light, microwave radiation.)

TABLE 2—AREAS OF INTEREST: OFFICE OF IN VITRO DIAGNOSTIC DEVICES AND RADIOLOGICAL HEALTH

Focus area	Specific areas of interest
Manufacturing of in vitro diagnostic devices	Preanalytical devices (i.e. blood tubes), pathogen collection devices, micro collection/transport devices; general reagents, manual reagents; general assays, common point-of-care devices.
Instrument training of medical devices (manufacturer or clinical laboratory).	Hands-on instrument and system training; clinical implication of common laboratory testing.
Quality system in manufacturing environments based on 21 CFR part 820.	Observation of implemented quality systems practices based on current good manufacturing practices.

B. Site Selection

The Center will be responsible for CDRH staff travel expenses associated with the site visits. CDRH will not provide funds to support the training provided by the site to the ELP General Training Program. Selection of potential facilities will be based on CDRH's priorities for staff training and resources available to fund this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding. If a site visit involves a visit to a separate physical location of another firm under

contract with the site, that firm must agree to participate in the ELP General Training program and must also have a satisfactory compliance history.

III. Request for Participation

Submit proposals for participation with the docket number found in the brackets in the heading of this document. Received requests may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

The proposal should include a description of your facility relative to focus areas described in table 1 or 2.

Please include the Area of Interest (see table 1 or 2) that the site visit will demonstrate to CDRH staff, a contact person, site visit location(s), length of site visit, proposed dates, and maximum number of CDRH staff that can be accommodated during a site visit. Proposals submitted without this minimum information will not be considered. In addition, please include an agenda outlining the proposed training for the site visit. A sample request and agenda are available on the ELP Web site at <http://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf> and <http://>

www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.

Dated: July 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-18662 Filed 8-6-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 materials, 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: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Udall Centers Review.

Date: August 21–22, 2014.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

Contact Person: Birgit Neuhuber, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-3562, neuhuber@ninds.nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; DMFP Contract Review.

Date: August 27–28, 2014.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Ernest Lyons, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-405, lyonse@ninds.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research

Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 1, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-18597 Filed 8-6-14; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4185-DR; Docket ID FEMA-2014-0003]

Nebraska; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Nebraska (FEMA-4185-DR), dated July 28, 2014, and related determinations.

DATES: *Effective Date:* July 28, 2014.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated July 28, 2014, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”), as follows:

I have determined that the damage in certain areas of the State of Nebraska resulting from severe storms, tornadoes, straight-line winds, and flooding during the period of June 1–4, 2014, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”). Therefore, I declare that such a major disaster exists in the State of Nebraska.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75

percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Christian Van Alstyne, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Nebraska have been designated as adversely affected by this major disaster:

Burt, Butler, Cass, Hamilton, Holt, Nemaha, Pawnee, Polk, Rock, Thurston, Valley, and Washington Counties for Public Assistance.

All counties within the State of Nebraska are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2014-18642 Filed 8-6-14; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4186-DR; Docket ID FEMA-2014-0003]

South Dakota; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.