

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
821.25(d) .....	1	1	1	1	1
Total .....					915

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

CFR section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per record	Total hours
821.25(b) .....	12	46,260	555,120	1	555,120
821.25(c) <sup>2</sup> .....	12	1	12	63	756
821.25(c)(3) .....	12	1,124	13,488	1	13,488
Total .....					569,364

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

<sup>2</sup> One time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1</sup>

21 CFR section	Number of respondents	Annual frequency of disclosure	Total annual disclosures	Hours per disclosure	Total hours
821.30(a) and (b) .....	17,000	1	17,000	1	17,000
821.30(c) and (d) .....	17,000	1	17,000	1	17,000
Total Hours .....					34,000

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

The annual hourly burden for respondents involved with medical device tracking is estimated to be 604,279 hours per year. The burden estimates cited in tables 1, 2, and 3 of this document are based on the number of device tracking orders issued in the last 3 years.

This regulation also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information found in 21 CFR 821.2(b), 821.25(e), and 821.30(e) have been approved under OMB control number 0910–0183.

Dated: November 5, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–28441 Filed 11–10–10; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2010–D–0319]

#### **Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled “Dear Health Care Provider Letters: Improving Communication of Important Safety Information.” Dear Health Care Provider (DHCP) Letters are correspondence—usually in the form of a mass mailing from the manufacturer or distributor of a human drug or biologic, or from FDA—intended to alert physicians and other health care providers to important new information about a marketed drug or biological product. This draft guidance provides recommendations on

when to use a DHCP letter, the types of information to include in a DHCP letter, how to organize that information, and formatting techniques to make the information more accessible. The draft guidance is intended to improve the quality of DHCP letters to make them more effective communication tools for new information about marketed products.

**DATES:** Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 11, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one

self-addressed adhesive label to assist those offices in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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:** Sandy Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4206, Silver Spring, MD 20993-0002, 301-796-2270; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled “Dear Health Care Provider Letters: Improving Communication of Important Safety Information.” Important new information about prescription drug and biological products emerges throughout a product’s lifecycle. For marketed products, there may be occasions when it is important to communicate new information promptly to health care practitioners involved in prescribing or dispensing a drug, or in caring for patients who receive a drug. The DHCP letter is an important mechanism (one of a number of different mechanisms) used to communicate important new information to health care professionals about a marketed product.

Formal and informal evaluations of DHCP letters have shown that the communication quality of DHCP letters—the extent to which the information is accessible and can be understood—varies widely. A study reported in 2005 evaluated the quality

of a group of DHCP letters sent during 2000 and 2001 that were intended to communicate important new drug safety information.<sup>1</sup> The study found that there is a correlation between the quality or perceived quality of a DHCP letter and the extent to which physicians perceive the new information as important. Letters that were evaluated as clearer, more concise, better organized and formatted, and focused on the most important aspects of the new safety information were considered to be more effective in communicating the new information.

FDA believes guidance concerning the format and content of the DHCP letter would be beneficial in improving the effectiveness of DHCP letters in communicating drug information. Accordingly, this draft guidance contains recommendations on when to use a DHCP letter, what types of information to include in a DHCP letter, how to organize that information, and formatting techniques to make the information in the letter more accessible.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on the format and content of DHCP letters. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Paperwork Reduction Act of 1995**

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or

provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA estimates the burden of this collection of information as follows:

Based on a review of MedWatch Safety Alerts for 2008 and 2009, we identified each Dear Health Care Provider Letter sent and the identity of each sponsor sending out a Dear Health Care Provider Letter for each year. We estimate that we will receive approximately 30 Dear Health Care Provider letters annually from approximately 25 application holders. FDA professionals familiar with Dear Health Care Provider Letters and with the recommendations in the draft guidance estimate that it should take an application holder approximately 100 hours to prepare and send Dear Health Care Provider Letters in accordance with the draft guidance. Therefore we estimate the annual reporting burden as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total hours
Annual Average .....	25	1.20	30	100	3,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this information collection.

<sup>1</sup> Mazor K, S. Andrade, J. Auger, *et al.*, “Communicating Safety Information to Physicians: An Examination of Dear Doctor Letters,” *Pharmacoepidemiol Drug Safety*, 14:869–875, 2005.

In the draft guidance, we refer to an earlier guidance for industry entitled "Using Electronic Means to Distribute Certain Product Information" (71 FR 26102, May 3, 2006). That guidance referred to previously approved collections of information found in FDA regulations that are subject to review by OMB. The collections of information in that guidance have been approved under OMB control number 0910-0249.

### III. 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.

### IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 5, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; 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:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Microbicide Innovation Program (MIP VI) (R21/R33).

*Date:* December 2-3, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites—Chevy Chase Pavilion, 4300 Military Rd. NW., Tenleytown Ballroom, Washington, DC 20015.

*Contact Person:* Roberta Binder, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, Room 3130, Bethesda, MD 20892-7616, (301) 496-7966, [rbinder@niaid.nih.gov](mailto:rbinder@niaid.nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Support for Conference and Scientific Meetings.

*Date:* December 6-8, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

*Contact Person:* B. Duane Price, PhD, Scientific Review Officer, Scientific Review Program, DHHS/NIH/NIAID/DEA, Room 3139, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301-451-2592, [pricebd@niaid.nih.gov](mailto:pricebd@niaid.nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Unsolicited R24.

*Date:* December 6, 2010.

*Time:* 10 a.m. to 11:30 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

*Contact Person:* Eleazar Cohen, PhD, Scientific Review Officer, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, Room 3129, Bethesda, MD 20892, 301-435-3564, [ec17w@nih.gov](mailto:ec17w@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 4, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-28457 Filed 11-10-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Dental & Craniofacial Research; 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 a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Dental & Craniofacial Research, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

*Date:* December 12-13, 2010.

*Time:* December 12, 2010, 7 p.m. to 9 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Time:* December 13, 2010, 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, Building 30, 30 Center Drive, 117, Bethesda, MD 20892.

*Contact Person:* Alicia J. Dombroski, PhD, Director, Division of Extramural Activities, Natl Inst of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892.

Information is also available on the Institute's/Center's home page: <http://www.nidcr.nih.gov/about/CouncilCommittees.asp>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: November 4, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-28460 Filed 11-10-10; 8:45 am]

**BILLING CODE 4140-01-P**