

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
810.15(b)	2	1	1	8	8

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

The burden estimates for tables 1 and 2 of this document are based on FDA's experience with voluntary recalls under part 810 of the regulations. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily. Since the last time this collection of information was submitted to OMB for renewal/approval, there has been one mandatory recall.

Dated: February 6, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-3098 Filed 2-9-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0096]

Draft Guidance for Industry on Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations." This guidance is intended to assist sponsors of clinical investigations in determining the amounts and types of safety data to collect in trials conducted late in the development of a drug for marketing approval or after approval based on what is already known about a drug's safety profile. Extensive safety data are collected in clinical trials of investigational drugs to support marketing approval (premarket) and trials conducted after approval (postmarket). FDA believes that more selective or targeted safety data collection may be possible for some late stage premarket trials and postmarket trials because certain aspects of a drug's safety profile will be sufficiently well-established that comprehensive data

collection is not needed. FDA believes more selective or targeted safety data collection in appropriate circumstances may improve the quality of the safety assessment without compromising the integrity of the trial results.

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 April 10, 2012.

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 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 that office 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: Lori Bickel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6353, Silver Spring, MD 20993, 301-796-0210; 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 entitled "Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical

Investigations." This guidance is intended to assist clinical trial sponsors in determining the amounts and types of safety data that should be collected during late-stage premarket and postmarket clinical investigations of a drug product based on what is already known about the safety profile of the drug.

To meaningfully weigh the risks and benefits of a drug, it is important to collect a broad range of safety-related data and develop a comprehensive safety profile of a drug. In some cases, however, certain aspects of the safety profile may be well-established prior to the completion of clinical trials to support marketing approval of an investigational drug. Similarly, for a marketed drug being studied for a new use, much of the existing safety profile for the approved use may be relevant to the new use. If certain aspects of a safety profile are well-established, it may not be necessary to collect certain types of safety data in clinical trials because the data would not contribute anything additional to the safety profile and may even have negative consequences (e.g., serve as a disincentive to clinical investigators). In those settings, more targeted or selective data collection can be used to focus on collecting data that will further contribute to the safety profile.

The draft guidance identifies the types of safety data collected and recommends more selective or targeted safety data collection in a variety of circumstances, offers suggestions on methods that may be used to conduct selective or targeted data collection where appropriate, and highlights circumstances in which comprehensive data collection is generally needed.

This draft guidance is being developed 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 determining the extent of safety data collection needed in late stage premarket and postapproval clinical investigations. 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. 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. 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.

III. 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/default.htm> or <http://www.regulations.gov>.

Dated: February 6, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel Multi-Center Study of Tamsulosin for Ureteral Stones in the Emergency Department.

Date: March 26, 2012.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy

Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, rushingp@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Collaborative Interdisciplinary Team Science in NIDDK Research Areas (R24)—Barrett's Oesophagus and IBD.

Date: March 30, 2012.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; LRP Reviews.

Date: March 30, 2012.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: D.G. Patel, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7682, pateldg@niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 6, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-3153 Filed 2-9-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Global Rare Diseases Patient Registry and Data Repository (GRDR) Notice and Request for Information (RFI)

SUMMARY: The Office of Rare Diseases Research (ORDR), an organizational component of the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health

(NIH), is inviting patient organizations without a patient registry and those with established patient registries to be considered for participation in a two-year pilot project to establish the Global Rare Diseases Patient Registry and Data Repository (GRDR), and to submit background information about their organization for consideration by the project's selection committee. More information may be found at <http://rarediseases.info.nih.gov/GRDR>.

The goal of the GRDR is to enable data analysis within and across many rare diseases and to facilitate clinical trials and other studies. An interface will be developed to accept de-identified patient data from existing patient registries to promote data sharing.

The GRDR will serve rare disease patients and their advocacy groups seeking help and information. It will also serve investigators conducting research, clinicians treating patients, epidemiologists analyzing disease data, and investigators seeking patients for new clinical trials and initiating natural history studies.

A researcher portal will allow authorized researchers to gain access to de-identified patient data to identify potential study candidates and to learn about the natural history of disease. Because the GRDR will contain only de-identified data, investigators will recruit prospective participants through the patient organizations. Direct contact with the prospective participants would occur only after the patient has granted permission.

In order to aggregate data from different registries to facilitate pan-disease analysis, data must be captured and collected in a standardized manner. Use of Common Data Elements (CDEs) facilitates the standardization of data collection and allows for harmonization, sharing, and exchange of information across registries. ORDR has developed a set of minimal CDEs that have been accepted and adopted by numerous national and international patient advocacy groups and professional organizations globally. To develop organ systems and disease specific CDEs, ORDR is coordinating and collaborating with the various NIH components, patient advocacy groups, and professional organizations that already have developed similar CDEs or are in the process of developing them.

The purpose of this pilot program is to test the different functionalities of the GRDR. A total of 24 organizations will be selected. Twelve organizations with established registries and 12 organizations that have no registry will be chosen to participate.