Adverse Event Pilot Program for Medical Devices—(OMB Control Number 0910–0471—Extension)

FDA is requesting approval from OMB for clearance to continue to conduct a pilot project to evaluate aspects of a national reporting system mandated by the Food and Drug Modernization Act (FDAMA) of 1997. Under section 519(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)(b)), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions; user facilities (hospitals, nursing homes, ambulatory surgical facilities and outpatient diagnostic and treatment facilities) to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 213 of FDAMA amended section 519(b) of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(b)). This amendment legislated the replacement of a universal user facility reporting by a system that is limited to a ''* * * subject of user facilities that constitutes a representative profile of user reports'' for device related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the act.

FDA is the regulatory agency responsible for the safety and effectiveness of medical products including medical devices and radiological products. Important questions about medical devices, such as those concerning user experience, durability, and rare effects may not be answered until after the device has been marketed. To protect the public health, FDA must be able to rapidly collect information pertaining to adverse events associated with medical devices after they have been marketed. This system is called the Medical Product Surveillance Network (MedSun). The current universal reporting system remains in place during the pilot stages of the new program, and until FDA implements the new national system by regulation. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high quality data on medical devices in clinical use.

Before writing a regulation to implement the large-scale national MedSun reporting system, FDA has been conducting a pilot project to ensure all aspects of the new system address the needs of both the reporting facilities and FDA. This pilot project began with a small sample (approximately 25) and was planned to increase to a larger sample of approximately 250 facilities over a period of approximately 3 years. Data collection began in February 2002 and has been increasing since that time. FDA has achieved its recruitment goals each year, reaching 180 sites at the end of fiscal year (FY) 2003. FDA will reach a total of 240 for FY 2004 and will reach the final goal of 250 by FY 2005. The program has proven to be very popular with sites as FDA has gained a national reputation, with hospitals waiting in line to join. However, FDA's current resources will not permit FDA to expand beyond 250 sites at this time.

The pilot originally had 3 parts to the data collection: (1) Collecting demographic profile information about the participation facilities, (2) implementing an electronic version of the portions of the MedWatch form (FDA Form No. 3500A, OMB control number 0910–0291) used to report adverse events occurring with medical devices, and (3) adding additional voluntary questions to the data collection. To date, these 3 features remain unchanged. However, there has been an addition to the data collection that was approved by OMB in the spring of 2004. Therefore, the fourth part of the collection system is the Medical Device Engineering Network (M–DEN)—a place on the MedSun software for the reporters to share information with each other.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Data Type	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
MedSun	250	8	2,000	.75	1,500
M–DEN	83	10	830	.50	415
Total					1,915

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

Currently, FDA has 180 sites participating in MedSun pilot program, but expects to have 250 sites over the next 2 years. The frequency of response reflects what FDA has actually been receiving as the average number of submissions in the MedSun Program. While 6 is the actual average for submissions, FDA hopes to increase this number to 8 once their educational materials reach potential respondents. The time estimated to respond is based on feedback FDA has received from current MedSun reporters.

At this time, FDA estimates that 1/3 of the total number of respondents will access M–DEN aspect of the MedSun software, or approximately 83 persons per year. Each respondent is expected to post 5 problems and respond to 5 problems posted by other MedSun participants for a total of 10 responses per year. It is expected that each visit to the bulletin will not take longer than 30 minutes.

Dated: January 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–1587 Filed 1–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0014]

Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions; 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 ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions.'' FDA is revising its March 2002 guidance

for industry of the same title to include guidance for sponsors who will be submitting information required by the Best Pharmaceuticals for Children Act (BPCA). The BPCA amended the Public Health Service Act (PHS Act) to require that additional information be included in the Clinical Trials Data Bank established as required by the Food and Drug Administration Modernization Act of 1997 (Modernization Act). This draft guidance explains how to provide that information.

DATES: Submit written or electronic comments on the draft guidance by March 29, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Theresa Toigo, Office of Special Health Issues (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4460.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions'' to assist sponsors who will be submitting information to the Clinical Trials Data Bank established by section 113 of the Modernization Act (42 U.S.C. 282). This draft guidance revises the guidance of the same title issued in March 2002 (67 FR 12022, March 18, 2002) to include assistance on submitting information required by the BPCA (Public Law 107–109). This draft guidance updates the March 2002 guidance.

The BPCA amends section 402(j)(3)(A) of the PHS Act (42 U.S.C. 282(j)(3)(A)) to require that additional information be included in the Clinical Trials Data Bank established as required under section 113 of the Modernization Act. Additional information to be submitted includes a description of whether, and through what procedure, the manufacturer or sponsor of an investigation of a new drug will respond to requests for a protocol exception, with appropriate safeguards, for single-patient and expanded access use of the investigational drug, particularly in children.

Section 113 of the Modernization Act, enacted November 21, 1997, directs the Secretary of Health and Human Services (the Secretary), acting through the Director of the National Institutes of Health (NIH), to establish, maintain, and operate a data bank of information on clinical trials for drugs to treat serious or life-threatening diseases and conditions. The Clinical Trials Data Bank is intended to be a central resource, providing current information on clinical trials to individuals with serious or life-threatening diseases or conditions, to other members of the public, and to health care providers and researchers.

Specifically, section 113 of the Modernization Act requires that the Clinical Trials Data Bank contain the following information: (1) Information about Federally and privately funded clinical trials for experimental treatments (drug and biological products) for patients with serious or life-threatening diseases or conditions, (2) a description of the purpose of each experimental drug, (3) patient eligibility criteria, (4) a description of the location of clinical trial sites, and (5) a point of contact for patients wanting to enroll in the trial. Section 113 of the Modernization Act also requires that information provided through the Clinical Trials Data Bank be in a form that can be readily understood by the public (42 U.S.C. 282(j)(3)(A)). The BPCA, signed by the President on January 4, 2002, requires that the Clinical Trials Data Bank contain additional information including a description of whether, and through what procedure, the manufacturer or sponsor of an IND will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded access use of the investigational drug, particularly in children.

The NIH, through its National Library of Medicine (NLM) and with input from FDA and others, developed the Clinical Trials Data Bank. The first version of the Clinical Trials Data Bank was made available to the public on February 29, 2000, on the Internet at *http://clinicaltrials.gov*. At that time, the data bank included primarily NIH-sponsored trials.

Shortly thereafter, FDA made available two draft guidances. The first draft guidance provided recommendations for industry on the submission of protocol information to the Clinical Trials Data Bank. It included information about the types of clinical trials for which submissions are required under section 113 of the Modernization Act as well as information about the content of those submissions. The second draft guidance addressed procedural issues, including how to submit required and voluntary protocol information to the Clinical Trials Data Bank. It also discussed issues related to submitting certification to the Secretary that disclosure of information for a particular protocol would substantially interfere with the timely enrollment of subjects in the clinical investigation. The second draft guidance also proposed a timeframe for submitting the information. The March 2002 guidance combined the two draft guidances into a single guidance (available at *http://www.fda.gov/cder/guidance/4856fnl.htm* or *http://www.fda.gov/cber/gdlns/clintrial.htm*).

This draft guidance updates the March 2002 guidance to include information on how to comply with new statutory requirements contained in the BPCA, for submitting details about single-patient use and expanded access use contained in the BPCA. This draft guidance also includes several minor updates to the information in it and to the format. Additional updates on procedural issues not related to the BPCA will be discussed in future revisions to the guidance.

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 information program on clinical trials for serious or life-threatening diseases and conditions. 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**) written or electronic

comments on the draft guidance. Submit two copies of mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination 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 *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 20, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–1591 Filed 1–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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: National Cancer Institute Special Emphasis Panel Multi-Center Clinical Trial for Aids.

Date: March 8, 2004.

Time: 1 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Shamala K. Srinivas, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8133, Bethesda, MD 20892, 301–594–1224.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 16, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–1708 Filed 1–26–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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: National Cancer Institute Special Emphasis Panel Prevention Research and Epidemiology.

Date: March 2–4, 2004.

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

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Mary Jane Slesinski, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8045, Bethesda, MD 20892, 301/594–1566.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 16, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–1709 Filed 1–26–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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: National Cancer Institute Special Emphasis Panel SPORE in Head and Neck Cancer.

Date: March 2–3, 2004.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Timothy C. Meeker, MD, Scientific Review Administrator, Special Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8088, Rockville, MD 20852, 301/594–1279.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 16, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–1710 Filed 1–26–04; 8:45 am]

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