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. 360(i)(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>
<thead>
<tr>
<th>Data Type</th>
<th>Number of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>MedSun</td>
<td>250</td>
<td>8</td>
<td>2,000</td>
<td>.75</td>
<td>1,500</td>
</tr>
<tr>
<td>M–DEN</td>
<td>83</td>
<td>10</td>
<td>830</td>
<td>.50</td>
<td>415</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,915</td>
</tr>
</tbody>
</table>

* 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.


Jeffrey Shuren,
Assistant Commissioner for Policy.

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 entitled “Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions.”
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://
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


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 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)


LaVerne Y. Stringfield,
Director, Office of Federal Advisory Committee Policy.
[FR Doc. 04–1710 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)


LaVerne Y. Stringfield,
Director, Office of Federal Advisory Committee Policy.
[FR Doc. 04–1710 Filed 1–26–04; 8:45 am]
BILLING CODE 4140–01–M