[FR Doc. E9–22001 Filed 9–11–09; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0407]

Pediatric Clinical Trials Workshop: Unmet Needs, Trial Designs and Clinically Meaningful Safety and Effectiveness Outcomes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Pediatric Clinical Trials Workshop: Unmet Needs, Trial Designs and Clinically Meaningful Safety and Effectiveness Outcomes.'' The purpose of the public workshop is to solicit information from primary and secondary health care providers, academia, industry, and professional societies on various aspects of device clinical trials involving pediatric diseases and patients. Information from this public workshop will help stimulate interest in pediatric device clinical trial research methods, and develop topics for further discussion regarding the safety of pediatric device clinical trials. The information gathered in this and future workshops will help to develop future guidance for developing safe clinical trials for devices intended for pediatric patients. We encourage participation and comments from workshop attendees on the topics and questions discussed. Please see instructions for registration and for providing comments in the sections of this document entitled ''*Registration*'' and ''*Comments*.''

Dates and Times: The public workshop will be held on October 29, 2009, from 8 a.m. to 5:30 p.m. and October 30, 2009, from 8 a.m. to 12 noon.

Location: The public workshop will be held at the Holiday Inn College Park located off I–95 at 10000 Baltimore Ave., College Park, MD 20740. The hotel front desk number is 1–301–345–6700. For directions, please refer to the meeting Web page: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm170938.htm*

Contact Person: Barbara Buch, Center For Devices and Radiological Health, Food and Drug Administration, Bldg. 66, rm. 1406, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5650, FAX: 301–847–8117, e-mail: *barbara.buch@fda.hhs.gov*. If you need special accommodations due to a disability, (such as wheelchair access or a sign language interpreter), please notify Barbara Buch by September 30, 2009.

Registration: Registration and seating will be on a first-come, first-served basis and discussion preference will be afforded to clinical research investigators involved in pediatric clinical device trials, health care givers, and patient advocates. Please provide your name, title, organization affiliation, address, and e-mail contact information. There is no registration fee to attend the workshop. There will be no onsite registration. Please register electronically at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* by September 30, 2009. Due to limited space, and to maximize participation, attendees are asked to delegate one or two representatives from their organizations to participate in the general sessions. A report of The Workshop and The Information presented will be available following the meeting via a link on the meeting Web page. If you wish to make an oral comment during or to attend the public workshop, please note this in your registration information. The online registration form will instruct you as to the information you should provide prior to the meeting. In general, a summary of the presentation and an electronic copy of the presentation should be submitted by October 1, 2009. We will try to accommodate all persons who wish to make oral comments during the general sessions. However, we strongly recommend that you provide written comments as instructed in this document to ensure that your opinion, comments, and suggestions are captured. Please refer to the section, ''*Comments*'' for instructions on how to submit written comments.

Comments: The deadline for submitting comments regarding this public workshop is November 30, 2009.

Regardless of attendance at the public workshop, interested persons may submit written or electronic comments. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Electronic comments should be submitted to *http://www.regulations.gov*. Comments should be identified 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.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding This Public Workshop?

The purpose of the public workshop is to solicit expert input on topics related to pediatric device clinical trials. The agency seeks discussion between FDA and other interested parties regarding the conduct of clinical trials to investigate device use in pediatric populations. Other purposes of the public workshop are, to identify any gaps in such research, and to provide information about evaluating the short- and long-term safety and effectiveness of pediatric medical devices using valid and sound scientific methods. Since the 2007 Food and Drug Administration Amendments Act was signed into law, there has been increased interest in conducting scientifically sound clinical research related to pediatric populations. It is hoped that this meeting will provide a forum for open discussion and information exchange among interested parties, FDA, and other stakeholders to lay a framework for further research into the use of devices to treat disorders and diseases that affect pediatric patients.

II. What Will Be the Format for the Meeting?

The format for the meeting will include a general session in the morning on the first day. Invited expert speakers will present information regarding current needs and concerns about clinical trials that involve pediatric patients. These presentations will provide the topics for the small breakout groups, which will begin in the afternoon session of day one and continue through the morning of day two of the public workshop. Each of the smaller breakout group discussion sessions will be led and moderated by a panel of experts in each of the specialty focus areas listed in section III of this document. Each small group session will begin with an invited presentation to describe the issues of concern in the specific specialty. This will be followed by a moderated question and comment session including both prespecified questions posed to the assembled group and any that arise during the workshop's discussions. Those in attendance will have the opportunity in these small group discussions to participate in the discussion, ask questions, and provide comments for consideration. Small group discussions will be concluded in the morning of day two. Small group participation will be limited by space and will be available on a first-come, first-served basis. When registering for

the meeting, you should also designate which small group discussion you would like to attend because each participant may register for only one of the small group sessions.

At the conclusion of day two's small group discussions, the general session will reconvene. After the general session reconvenes, each small group will report to the general session the results of the discussions related to the general questions posed to each group in outline form.

III. What Are the General Topic Areas We Intend to Address at the Public Workshop?

We plan to discuss a number of general disease/anatomical topical issues at the conference, including the following issues:

- Musculoskeletal disease,
- Cardiovascular disease,
- Abdominal disorders and gastrointestinal (GI) diseases,
- Neurologic disorders and conditions,
- Renal diseases, and
- Audiologic disorders.

The challenges posed by developing diagnostic tests for pediatric patients will be addressed as a part of discussion under each topical area breakout session. For each of the general disease/anatomical topic areas, we will pose questions to elicit and solicit scientific and clinical discussion in the breakout sessions. These include, but are not limited to the following questions:

What are the most urgent unmet needs?

What are the best practices for conduct of clinical research, including clinical trial design?

What are specific patient/caregiver issues to consider?

What are the surrogate endpoints for lifelong patient safety and effectiveness?

What are appropriate clinical assessments?

What are appropriate endpoints that determine clinical success?

The questions, listed in section IV of this document, will be the focus of the expert-moderated breakout discussions in the afternoon of day one and the morning of day two.

IV. What Are the Issues That Will Be Discussed and Considered?

Questions for Discussion Regarding Pediatric Device Clinical Trials

1. What Are the Five Most Important Unmet Research Needs in Each Specific Disease/Anatomic Category? (musculoskeletal disease, cardiovascular disease, abdominal disorders and GI diseases, neurologic disorders and conditions, renal diseases, and audiologic disorders)

Although there are obvious barriers to clinical trials such as concerns about the effects on child development, there are significant needs in both rare and common diseases or disorders that have not been met with modifications of adult devices. We will start by asking questions such as:

a. What are the most important unmet device needs in each category?

b. What are the scientific or clinical barriers or other potential barriers to developing devices to meet those needs?

2. What Are Some Clinical Trial Designs That Encourage Enrollment of Pediatric Patients While Providing Quality Data to Support Safety and Effectiveness of Devices?

We need to understand:

a. What are appropriate controls to use in pediatric trials to satisfy the legal regulatory definitions of valid scientific evidence as described in 21 CFR 860.7?

b. How can followup be maximized?

c. What timeframes are needed given the age of patients and the expected lifetime of the device/disease being treated?

d. How do we understand the long term effect on development and growth in a short clinical trial?

3. Preclinical and Animal Studies

Although there are examples of immature and fetal animal studies that are well established for pharmaceuticals, how do we translate those concepts for devices?

a. What types of endpoints and timeframes translate into outcomes in the human population? How do we know that?

b. How do we set a standard to judge subsequent trial outcomes as acceptable and safe?

c. What animal models exist or are appropriate for studying each of the diseases or disorders we identify as significant unmet needs?

4. How Do We Measure Safety and Effectiveness in a Pediatric Population?

The pediatric population cannot always describe symptoms or functional problems in the same way that adults can. It therefore follows that the same assessment tools and surrogate endpoints will not apply to a pediatric population.

Therefore we are striving to understand:

a. What validated assessments are needed or exist for the pediatric population being treated?

b. What surrogate markers or endpoints are needed for each disease?

c. What surrogates are needed or are available to determine long-term outcomes?

d. How do we validate surrogate endpoints?

5. How Do We Know That the Study and the Treatment Are Successful?

Assessment and judgment of patient outcomes varies considerably for a pediatric population. The needs of the patient and his caregiver or parent must be considered. The longevity of, and durability of, devices captures a new meaning when the lifespan is 50 to 60 years; remaining lifespan in adults is very different. We are soliciting feedback on:

a. What constitutes successful or unsuccessful treatment outcomes?

b. What criteria should be used to determine successful or unsuccessful treatment outcomes?

c. What human factors in each case need to be considered?

d. What patient factors unique to the pediatric population have to be considered?

e. What criteria are required to acknowledge that successful treatment for a patient has been achieved?

f. What constitutes a successful clinical trial?

g. How long should a device or treatment last to be considered effective?

Please note funding options for research have already been discussed at prior public meetings and will not be discussed at this workshop. Information regarding funding sources is available on government Web sites as well as other public Web sites dedicated to pediatric health.

V. Where Can I Find Out More About This Public Workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*.

Organization and Basic Instructions for Comments

To facilitate information gathering, we invite written comments on the questions presented in section IV of this document. We intend to discuss and expand on these same questions during the small group discussions. If you wish to comment in writing on a particular question, please identify the question that you are addressing before providing your response to the question. For example, your comment could take the following format:

''Question 1—[Quote the question].''

''Response—[Insert your response].''

You do not have to address each question. Additionally, for those questions pertaining to the prevalence of a particular need, problem or scientific question, please provide data and/or references so that we may understand the basis for your comment, figures, and any assumptions that you used. Additionally, the goal of this public workshop is to gain a greater understanding of treatment needs and needs for innovative solutions to those needs. Accordingly, we look forward to participation and comments from manufacturers, innovators, and organizations that either market or have in development technologies that could be used to treat pediatric patients.

Dated: September 3, 2009.

Catherine M. Cook,

Associate Director for Regulations and Policy, Center for Devices and Radiological Health.

[FR Doc. E9–22012 Filed 9–11–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

National Protection and Programs Directorate; Methodology Technical Implementation Functional Survey

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 60–Day notice and request for comments; new information collection request, 1670–NEW.

SUMMARY: The Department of Homeland Security, National Protection and Programs Directorate, has submitted the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until November 13, 2009. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to Lisa Hormann, Infrastructure Information Collection Division, DHS/NPPD/IP/IICD, *Lisa.hormann@associates.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Methodology Technical Implementation (MTI) Project Office supports the 18 critical infrastructure and key resource (CIKR) sectors by integrating risk and vulnerability assessment methodologies into automated tools. MTI efforts address the unique needs and requirements of each sector by working with sector partners to develop tailored solutions that enable the identification, analysis, and management of sector-specific security risks. The MTI team collaborates with Sector-Specific Agencies (SSAs), Sector and Government Coordinating Councils (SCCs and GCCs), and divisions within the Department of Homeland Security's Office of Infrastructure Protection. The MTI team also works with sector specialists, risk analysts, private sector individuals, and Federal agency representatives. Efficient and effective use of the MTI tools helps all CIKR sectors nationwide reach their goal of making their sectors safer and provides a way to comply with recommendations in the National Infrastructure Protection Plan (NIPP). To ensure that interested stakeholders achieve this mission, MTI requests opinions and information from users of the tool regarding tool functions and improvements.

The MTI Project Office is administered out of the Infrastructure Information Collection Division (IICD) in the Office of Infrastructure Protection (IP). The survey data collected is for internal MTI, IICD and IP use only. The MTI Project Office will use the results of the Functional Survey to determine levels of customer satisfaction with the MTI tools and prioritize future improvements of key tool functions. The results will also allow the program to appropriate funds cost-effectively based on user need, and cost savings while improving the tool.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security, National Protection and Programs Directorate.

Title: MTI Functional Survey.

OMB Number: 1670–NEW.

Frequency: Annual.

Affected Public: Business or other for profit.

Number of Respondents: 5,500.

Estimated Time Per Respondent: 15 minutes (.25 hours).

Total Burden Hours: 1375 annual burden hours.

Total Burden Cost (operating/maintaining): $20,520.

Thomas Chase Garwood, III,

Chief Information Officer, National Protection and Programs Directorate, Department of Homeland Security.

[FR Doc. E9–22053 Filed 9–11–09; 8:45 am]

BILLING CODE 9910–9P–P

DEPARTMENT OF HOMELAND SECURITY

National Protection and Programs Directorate; Assessment Questionnaire—Risk Self Assessment Tool (R–SAT)

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 60-Day notice and request for comments; new information collection request, 1670–NEW.

SUMMARY: The Department of Homeland Security, National Protection and Programs Directorate, has submitted the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until November 13, 2009. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Comments and questions about this Information Collection