statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 3, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 6, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Dr. Carlos Peña at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 19, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–6796 Filed 3–25–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0145]

Developing a Consolidated Pediatric Rheumatology Observational Registry; Public Workshop

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 ''Developing a Consolidated Pediatric Rheumatology Observational Registry.'' This 2-day public workshop is intended to seek constructive input from key stakeholders in the pediatric rheumatology community, the pharmaceutical industry and the public to explore the value and feasibility of developing a consolidated pediatric rheumatology observational registry.

DATES: The public workshop will be held on May 12, 2009, from 8:30 a.m. to 5 p.m. and on May 13, 2009, from 8:30 a.m. to noon. Register by April 21, 2009, to make a presentation at the workshop. See section III of this document for information on how to attend or present at the workshop. We are opening a docket to receive your written or electronic comments. Written or electronic comments must be submitted to the docket by July 14, 2009.

ADDRESSES: The public workshop will be held at the Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910 (Metro: Silver Spring Station on the Red Line). Submit written or electronic requests to make a presentation to Diane Ehrlich (see **FOR FURTHER INFORMATION CONTACT**).

Submit written comments 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.regulations.gov*. All comments should be identified with the docket number found in brackets in the heading of this document.

Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the workshop.

FOR FURTHER INFORMATION CONTACT: Diane Ehrlich, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6190, Silver Spring, MD 20993–0002, 301–796–3452, FAX: 301–847–8753, e-mail: *Diane.Ehrlich@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Currently, approved drug and therapeutic biological products for patients with juvenile idiopathic arthritis (JIA) (or juvenile rheumatoid arthritis (JRA)) are monitored for long-term safety beyond the information available at the time of approval on a product-by-product basis using registries mandated by FDA's postmarketing requirements. FDA is addressing concerns raised by individuals in the pediatric rheumatology community about the current approach of using product-specific pediatric rheumatology observational safety registries. Some of the concerns expressed include the following:

1. It is difficult to capture important information from children and adolescents whose medication is switched over time because long-term data on these patients will not be available under the product specific registries. Patients on ''real-life'' combinations of medications and/or nonstandard doses are often not included in product-specific registries.

2. Current registries do not always provide an adequate control group to assess background rates of important adverse events.

3. The limited number of patients with JIA will make adequate enrollment in product-specific observational registries more difficult as the number of approved drug and biological products increases.

4. A nonproprietary registry rather than a proprietary registry would allow wider access to the safety data that is collected.

5. A consolidated pediatric rheumatology observational registry may allow more efficient identification of longer term safety issues in this population.

II. Scope of Public Workshop

At the public workshop, FDA will present its current thinking on the use of product-specific postmarketing registries to capture long-term safety data of drug and biological products administered to patients with JIA. Product-specific registries will be compared with a consolidated pediatric rheumatology observational registry that could meet the regulatory postmarketing requirements of FDA and also collect other safety information and support potential research initiatives.

A. Objectives of the Workshop

The workshop objectives are as follows:

1. Discuss potential registry models, taking into account existing registries for other diseases and in other countries.

2. Discuss the advantages and disadvantages of a common consolidated registry for JIA, taking into account:

- The pediatric rheumatology perspective.
- The pharmaceutical company perspective.

3. Discuss methods to capture information regarding safety signals in rare diseases.

4. Discuss the value of working through existing large pediatric

rheumatology collaborative networks, such as the Childhood Arthritis and Rheumatology Research Alliance or the Pediatric Rheumatology Collaborative Study Group.

5. Define, for phase 4 studies in JIA patients, the database standards and elements of data collection (e.g., data quality, monitoring) that are necessary and sufficient to meet FDA regulatory requirements.

6. Discuss how pertinent research initiatives can be accomplished in the framework of a consolidated JIA registry, including:

- Ethical considerations.
- Data sharing considerations.

7. Discuss the options for funding a consolidated JIA registry.

B. Issues for Comment

FDA is interested in obtaining public comment on the following issues relating to development of a consolidated pediatric rheumatology observational registry:

1. Should we transition from product-specific registries to a consolidated pediatric rheumatology observational registry?

2. Currently, the product-specific registries are conducted by the individual sponsors of the approved drugs and/or biological products with the safety data submitted to FDA.

- How should a consolidated pediatric rheumatology observational registry be structured to collect data and conduct analyses to meet the standards for postmarketing requirements set by FDA and provide information about long-term safety?
- What hurdles must be overcome to transition from product-specific registries to a consolidated pediatric rheumatology observational registry (e.g., industry concerns, pediatric rheumatology community concerns, proprietary issues of longer term data and informed consent, fulfilling FDA regulatory requirements, challenges of registry funding, management and ownership or sharing of data)?

3. What data should be collected in a consolidated pediatric rheumatology observational registry? Consider the following topics:

Database standards and terminology (e.g., compatibility with large databases).

Necessary and sufficient data elements (e.g., safety, effectiveness, growth and development, comorbidities, tracking medication switches over time, as well as concurrent medication).

Length of individual patients' participation and overall duration of the consolidated pediatric rheumatology observational registry (e.g., managing pediatric data through and beyond the age of consent).

4. What are the optimal methods to analyze data from a consolidated pediatric rheumatology observational registry to identify safety signals? For example, should the methods define risk windows for attribution to a drug or biological product; internal controls; and/or analyses of confounding by indication, switches in medication, and multiple concurrent medications?

5. What are the opportunities for research initiatives within a consolidated observational rheumatology registry?

III. Attendance and Registration to Speak

There is no fee to attend the workshop, and attendees who do not wish to make an oral presentation do not need to register. Seating will be on a first-come, first-served basis.

If you would like to make an oral presentation during the open public session on day one of the workshop, you must register and provide an abstract of your presentation by close of business on April 21, 2009. To speak, submit your name, title, business affiliation (if applicable), address, telephone and fax numbers, and e-mail address to Diane Ehrlich (see **FOR FURTHER INFORMATION CONTACT**). FDA has included questions for comment in section II of this document. You should also identify by number each question you wish to address in your presentation, and the approximate time requested for your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Persons registered to make an oral presentation should check in before the workshop.

Ample time will be allowed during the scheduled agenda for attendees to ask questions of panelists. In addition, we strongly encourage written comments to the docket. Written or electronic comments will be accepted until July 14, 2009.

If you need special accommodations because of disability, please contact Diane Ehrlich (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

IV. Comments

Regardless of attendance at the public workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by July 14, 2009 (see **DATES**). Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcript

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: March 19, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6709 Filed 3–25–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(a) 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 open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Gestational Diabetes Life-Course Study.

Date: April 20, 2009.

Time: 2 p.m. to 3:30 p.m.

Agenda: To provide concept review of proposed concept review.