TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 741(d) of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
741(d)—Minor Use or Minor Species Fee Waiver & Reduction Requests	9	1	9	2	18
Request for Reconsideration; CVM AGDUFA Waiver Officer[2]	1	1	1	1	1
Request for Review; CVM AGDUFA Appeals Officer	1	1	1	1	1
Request for Review; FDA User Fee Appeals Officer	1	1	1	1	1
Total					21

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] CVM means Center for Veterinary Medicine.

Appeals for reconsideration or review of AGDUFA user fee waiver decisions will be very rare. Waivers are granted only for user fees involving minor use or minor species as defined by the Minor Use and Minor Species Act of 2008 (MUMS). Decisions on waivers of user fees based on minor species do not allow for agency discretion as ''minor species'' is defined specifically in the MUMS statute. As to minor use in a major species, FDA, under MUMS, determines that a new animal drug is for minor use in a major species at the time that the pioneer new animal drug application is submitted. This determination carries over to the abbreviated (generic) new animal drug application. Therefore, we do not anticipate that there will be more than one request for review or reconsideration for either the ''minor use'' or ''minor species'' waivers or reductions under AGDUFA per year.

Fee Waiver or Reduction Requests: For those who, after reading the guidance, decide to apply for a waiver or reduction of one or more of the fees they were assessed, the time to complete the information required for their waiver application, based on the guidance provided, is estimated to be 2 hours or less.

Based on FDA's database system, there are an estimated 50 sponsors of products subject to AGDUFA. However, not all sponsors will have submissions in a given year. CVM estimates nine waiver requests that include minor use or minor species. The estimated hours per response are based on past FDA experience with the various waiver requests in CVM. The hours per response listed in table 1 of this document are based on the average of these estimates.

Dated: March 19, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6724 Filed 3–25–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Joint Meeting of the Pediatric Advisory Committee and the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee and Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Monday, April 27, 2009, from 8 a.m. to 6 p.m.

Addresses: Washington DC North/ Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Carlos Peña, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14B–08), Rockville, MD 20857, 301–827–3340, or by e-mail: *carlos.peña@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On Monday, April 27, 2009, the Pediatric Advisory Committee and the Oncologic Drugs Advisory Committee will meet to discuss the scientific and ethical issues involved in obtaining and using brain biopsy specimens to evaluate gene expression patterns in children with diffuse pontine gliomas.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2009 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 13, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief

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]

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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