

Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information

is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Veterinary Feed Directive—21 CFR Part 558 (OMB Control Number 0910-0363)—Extension**

With passage of the Animal Drug Availability Act, Congress enacted legislation establishing a new class of restricted feed use drugs called Veterinary Feed Directive (VFD drugs).

The VFD class of drugs may be distributed without involving State pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to controls for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 503(f)), the implementing VFD regulation under section 558.6 (21 CFR 558.6) is tailored to the unique circumstances relating to the distribution of medicated feeds. The content of the VFD is spelled out in the regulation. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute, and the distribution records of all medicated feeds containing VFD must be maintained. The VFD regulation ensures the protection of the public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
558.6(a)(3) through (a)(5)	15,000	25	375,000	.25	93,750
558.6(d)(1)(i) through (d)(1)(iii)	300	1	300	.25	75
558.6(d)(1)(iv)	20	1	20	.25	5
558.6(d)(2)	1,000	5	5,000	.25	1,250
514.1(b)(9)	1	1	1	3.00	3
<b>Total</b>	<b>16,321</b>				<b>95,083</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through (e)(4)	5,000	75	375,000	.0167	6,263
<b>Total</b>	<b>117,500</b>				<b>25,051</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the times required for record preparation and maintenance is based on agency communication with industry and agency records and experience.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic

comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: May 28, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; 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:* Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

*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 July 22 and 23, 2008, from 8:30 a.m. to 5 p.m.

*Location:* Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person:* Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [Diem.Ngo@fda.hhs.gov](mailto:Diem.Ngo@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in the Washington, DC area), code 3014512539. 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 July 22, 2008, the committee will do the following: (1) Receive presentations from the Office of Pharmaceutical Science (OPS) and discuss current thinking on issues pertaining to the use of nanotechnology in drug manufacturing, drug delivery, or drug products, and (2) receive an update from OPS, discuss, and make comments on current strategies and directions for the testing of lead in pharmaceutical products.

On July 23, 2008, the committee will do the following: (1) Receive and discuss presentations from the Office of Generic Drugs (OGD) on the bioequivalence methods for locally acting drugs that treat gastrointestinal (GI) conditions, (2) receive and discuss presentations from OGD on the use of inhaled corticosteroid dose-response as a means to establish bioequivalence of inhalation drug products, and (3) receive and discuss presentations from OPS on the drug classification of orally

disintegrating tablets (ODT) as a separate dosage form, and the need for subsequent guidance on expectations and recommendations that would be required for applications proposing the dosage form.

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 2008 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 July 8, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. 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 June 30, 2008. 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 July 1, 2008.

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 Diem-Kieu Ngo 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: May 27, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Arthritis 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:* Arthritis 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 July 29, 2008, from 8:30 a.m. to 3:30 p.m.

*Location:* Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

*Contact Person:* Nicole Vesely, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, Rm. 1093), Rockville, MD 20857, 301-827-6793, FAX: 301-827-6776, e-mail: [nicole.vesely@fda.hhs.gov](mailto:nicole.vesely@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512532. 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:* The committee will discuss biologics license application (BLA) 125276, ACTEMRA (tocilizumab),