

welfare agency recruitment and collection of files for sampling children, and Phase 2 includes baseline data collection and an 18-month follow-up data collection. The current data collection plan calls for selecting a new cohort of 4,565 children and families and repeating similar data collection

procedures as the previous two cohorts. This Notice is specific to Phase 1. The overall goal is to recruit child welfare agencies in 83 primary sampling units nationwide. Child welfare agencies will be selected with probability proportional to size, based on the current distributions in the child

welfare system. Child welfare agency recruitment will include: mail, email, phone calls, and site visits with child welfare agency administrators.

*Respondents:* Child welfare agency administrators and other personnel. Data collection will take place over a 2-year period.

#### ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Information package for agency administrators .....	114	57	1	0.25	14
Initial call with agency staff .....	114	57	1	1	57
In-person visit with agency staff .....	20	10	1	1	10
Visit or call with agency staff explaining the sample file process .....	83	42	1	2	84
Agency staff monthly sample file generation and transmission .....	83	42	15	1	630

*Estimated Total Annual Burden Hours:* 795.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street, SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Email: OIRA\_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*ACF Certifying Officer.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

##### Arthritis Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Arthritis Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will be held on July 13, 2016, from 7:30 a.m. to 5 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

##### FOR FURTHER INFORMATION CONTACT:

Moon Hee Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, [AAC@fda.hhs.gov](mailto:AAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-

741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

##### SUPPLEMENTARY INFORMATION:

*Agenda:* The committee will discuss biologics license application 761042, for GP2015, a proposed biosimilar to Amgen Inc.'s ENBREL (etanercept) submitted by Sandoz, Inc. The proposed indications (uses) for this product are: (1) Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (in combination with methotrexate (MTX) or used alone); (2) reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older; (3) reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (in combination with MTX in patients who do not respond adequately to MTX alone); (4) reducing signs and symptoms in patients with active ankylosing spondylitis; and (5) treatment of adult patients (18 years or older) with chronic

moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

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/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting 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 June 28, 2016. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 3 p.m. Those individuals interested in making 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 20, 2016. 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 June 21, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Moon Hee Choi 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.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: June 6, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0511]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medicated Feed Mill License Application

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 11, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0337. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Medicated Feed Mill License Application—21 CFR Part 515—OMB Control Number 0910-0337—Revision

Feed manufacturers that seek to manufacture feed using Category II, Type A medicated articles or manufacture certain liquid and free-choice feed, using Category I, Type A medicated articles that must follow proprietary formulas or specifications are required to obtain a facility license under section 512 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b). Our regulations in part 515 (21 CFR part 515) establish the procedures associated with applying for a facility license. We require that a manufacturer seeking a facility license submit a completed medicated feed mill license application using Form FDA 3448 (21 CFR 515.10(b)). We use the information submitted to establish that the applicant has made the certifications required by section 512 of the FD&C Act, to register the mill, and to schedule a pre-approval inspection. We have made minor editorial revisions to Form FDA 3448, including the addition of a dedicated field for the submitter's email address in the contact information section. We estimate that the revisions will not change the amount of time necessary to complete the form.

We require the submission of a supplemental medicated feed mill license application for a change in facility ownership or a change in facility address (§ 515.11(b)). If a licensed facility is no longer manufacturing medicated animal feed under § 515.23, a manufacturer may request voluntary revocation of a medicated feed mill license. An applicant also has the right to file a request for hearing under § 515.30(c) to give reasons why a medicated feed mill license should not be refused or revoked.

In the **Federal Register** of March 9, 2016 (81 FR 12509), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment, which was not responsive to the comment request.

We estimate the burden of this collection of information as follows: