

support them in the requirements development phase of the acquisition lifecycle.

- The FFRDC must function so effectively as to act as an agent for the sponsor in the design and pursuit of mission goals.

- The FFRDC must provide rapid responsiveness to changing requirements for personnel in all aspects of strategic, technical and program management.

- The FFRDC must recognize government objectives as its own objectives, partnering with the sponsor in pursuit of excellence in public service.

- The FFRDC must allow for non-sponsor, other than CMS, work for operating Divisions within DHHS.

We are publishing this notice in accordance with 48 CFR 5.205(b) of the Federal Acquisition Regulations (FAR), to enable interested members of the public to provide comments on this proposed action. We note that this is the

second of three notices issued under the FAR.

The Request for Proposal will be posted on FedBizOpps in the Summer of 2011. Alternatively, a copy can be received by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

Dated: May 4, 2011.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011-11708 Filed 5-12-11; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: OCSE-157 Child Support Enforcement Program Annual Data Report.

OMB No.: 0970-0177.

Description: The information obtained from this form will be used to: (1) Report Child Support Enforcement activities to the Congress as required by law; (2) calculate incentive measures performance and performance indicators utilized in the program; and (3) assist the Office of Child Support Enforcement (OCSE) in monitoring and evaluating State Child Support programs. OCSE is proposing minor changes to the OCSE-157 report instructions for medical support line items that will provide states with the option to define medical support to include private health insurance as well as other health care coverage such as Medicaid, Children's Health Insurance Program (CHIP) and other state coverage plans, and cash medical support. Further legislative or regulatory changes may be necessary to update medical child support policy.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE-157	54	1	7	378
Estimated Total Annual Burden Hours:	378

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection. The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,
Reports Clearance Officer.

[FR Doc. 2011-11796 Filed 5-12-11; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0015]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Drugs; Common European Medicines Agency/ Food and Drug Administration Application Form for Orphan Medicinal Product Designation (Form FDA 3671)

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 June 13, 2011.

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 e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0167. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, *Jonnalynn.Capezzuto@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:

Orphan Drugs; Common EMA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671)—21 CFR Part 316—(OMB Control Number 0910-0167)—Extension

Sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360aa through 360 dd) give FDA statutory authority to do the following: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an “open protocol” basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in

the FD& C Act and sets forth procedures FDA will use in administering the FD& C Act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Based on past experience, the FDA estimates that there will be two respondents to §§ 316.10, 316.12, and 316.14 requiring 200 hours of human resources annually.

Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.21 specifies content of a request for orphan drug designation required for verification of orphan-drug status. Section 316.26 allows an applicant to amend the applications under certain circumstances. The Common European Medicines Agency (EMA)/FDA Application Form for Orphan Medicinal Product Designation (form FDA 3671) is intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from both the European Commission and FDA by reducing the burden of preparing separate applications to meet the regulatory requirements in each jurisdiction. It highlights the regulatory cooperation between the United States and the European Union mandated by

the Transatlantic Economic Council. The FDA does not believe the new form will result in any increased burden on the respondents and therefore we estimate no additional burden. Based on past experience, FDA estimates there will be 214 respondents requiring 64,200 hours of human resources annually. Section 316.22 specifies requirement of a permanent resident agent for foreign sponsors. Based on past experience, FDA estimates 55 respondents requiring 110 hours of human resources annually. Section 316.27 specifies content of a change in ownership of orphan-drug designation. Based on past experience, FDA estimates 43 respondents requiring 215 hours of human resources annually. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. Based on number of orphan-drug designations, the number of respondents is estimated as 1,652 requiring 4,956 hours of human resources annually. Finally, § 316.36 describes information required of sponsor when there is insufficient quantity of approved orphan drug. Based on past experience, FDA estimates 1 respondent requiring 45 hours of human resources annually.

The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

In the **Federal Register** of January 21, 2011 (76 FR 3910), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section and FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
316.10, 316.12, and 316.14	2	1	2	100	200
316.20, 316.21, and 316.26 Form FDA 3671	214	2	428	150	64,200
316.22	55	1	55	2	110
316.27	43	1	43	5	215
316.30	1,652	1	1,652	3	4,956
316.36	1	3	3	15	45
Total					69,726

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

Dated: May 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-11744 Filed 5-12-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0355]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 27, 2010 (75 FR 59266), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0606. The approval expires on February 28, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: May 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-11743 Filed 5-12-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-P-0128]

Determination That XIBROM (Bromfenac Ophthalmic Solution) 0.09% Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that XIBROM (bromfenac ophthalmic solution) 0.09% was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for bromfenac ophthalmic solution 0.09% if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6368, Silver Spring, MD 20993-0002, 301-796-3522.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA

for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

XIBROM (bromfenac ophthalmic solution) 0.09% is the subject of NDA 021664 held by ISTA Pharmaceuticals, Inc. (Ista), approved March 24, 2005. XIBROM is a topical nonsteroidal anti-inflammatory drug for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction.

In a citizen petition dated March 1, 2011, and in a letter dated March 3, 2011, Ista informed FDA that it had discontinued shipping XIBROM (bromfenac ophthalmic solution) 0.09% as of February 28, 2011. Ista took the position that XIBROM (bromfenac ophthalmic solution) 0.09% had been discontinued for safety reasons.

After considering the citizen petition and reviewing Agency records, FDA determined under § 314.161 that XIBROM (bromfenac ophthalmic solution) 0.09% was not withdrawn for reasons of safety or effectiveness. We described the basis for this determination in our letter response to Ista's citizen petition (available on <http://www.regulations.gov> under Docket No. FDA-2011-P-0128).

Accordingly, the Agency will continue to list XIBROM (bromfenac ophthalmic solution) 0.09% in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to XIBROM (bromfenac ophthalmic solution) 0.09% may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.