

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title:

Form OCSE-396, "Child Support Enforcement Program Quarterly Financial Report"

Form OCSE-34, "Child Support Enforcement Program Quarterly Collection Report"

OMB No.: 0970-0181.

Description: Form OCSE-396 and Form OCSE-34 are financial reports submitted following the end of each fiscal quarter by grantees administering the Child Support Enforcement Program in accordance with plans approved

under title IV-D of the Social Security Act. Submission of these forms enables grantees to meet their statutory and regulatory requirement to report program expenditures and child support collections, respectively, from the previous fiscal quarter.

States use Form OCSE-396 to report quarterly expenditures made in the previous quarter and to estimate program expenditures to be made and the incentive payments to be earned in the upcoming quarter. The Administration for Children and Families provides Federal funding to States for the Child Support Enforcement Program at the rate of 66 percent for all allowable and legitimate administrative costs of this program.

Tribes use OMB Form SF-425 to report quarterly expenditures made in the previous quarter. Form SF-425 is not included as part of this comment request.

States and Tribes use Form OCSE-34 to report child support collection activity during the previous quarter, including collections received, the distribution and disbursement of collections and any collections remaining undistributed.

The information collected in these reports is used by this agency to calculate quarterly Federal grant awards and incentive payments to States, to enable oversight of the financial management of the program for both States and Tribes and may be included in statistical and financial reports available to the public.

Respondents: 54 States (including Puerto Rico, Guam, the Virgin Islands and the District of Columbia) for Forms OCSE-396 and OCSE-34 plus approximately 60 Tribes for Form OCSE-34.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE-396	54	4	4	864
OCSE-34	114	4	9	4,104

Estimated Total Annual Burden Hours: 4,968.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chap 35), 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 Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email 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. 2017-02979 Filed 2-14-17; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Bioequivalence Recommendations for Difluprednate; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a revised draft guidance for industry on generic difluprednate emulsion, entitled "Draft Guidance on Difluprednate." The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support

abbreviated new drug applications (ANDAs) for difluprednate emulsion.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 17, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that

identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2007-D-0369 for “Draft Guidance on Difluprednate.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” will be publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more

information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993-0002, 301-796-5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE guidances available to the public on FDA’s Web site at <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific BE guidances and to provide a meaningful opportunity for the public to consider and comment on the guidance. This notice announces the availability of revised draft BE recommendations for generic difluprednate emulsion.

FDA initially approved new drug application 022212 for DUREZOL (difluprednate emulsion) in June 2008. In January 2016, FDA issued a draft guidance for industry on BE recommendations for generic difluprednate emulsion. We are now issuing a revised draft guidance for

industry on BE recommendations for difluprednate emulsion (“Draft Guidance on Difluprednate”).

In September 2016, Alcon Pharmaceuticals, Ltd. and its affiliated company, Novartis Pharmaceuticals Corporation, submitted a citizen petition requesting that FDA take several actions with respect to ANDAs for difluprednate emulsion, including regarding the demonstration of BE for any ANDA referencing DUREZOL. FDA has reviewed the issues raised in this citizen petition and is responding to the citizen petition separately in the docket for that citizen petition (Docket No. FDA-2016-P-2781, available at <http://www.regulations.gov>).

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the design of BE studies to support ANDAs for difluprednate emulsion. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-02972 Filed 2-14-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.