

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Grants to States for Access and Visitation

OMB No.: 0970-0204

Description: On an annual basis, States must provide OCSE with data on programs that the Grants to States for Access and Visitation Program has funded. These program reporting requirements include, but are not limited to, the collection of data on the number of parents served, types of services delivered, program outcomes, client socio economic data, referrals

sources, and other relevant data including the number of noncustodial parents who were able to obtain increased parenting time with their children.

Respondents: State Child Access and Visitation Programs and State and/or local service providers.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Online Portal Survey by States and Jurisdictions | 54 | 1 | 16 | 864 |
| Survey of local service grantees | 331 | 1 | 16 | 5,296 |

Estimated Total Annual Burden Hours: 6,160.

In compliance with the requirements of section 506(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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, 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. 2015-08842 Filed 4-16-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-E-0152]

Determination of Regulatory Review Period for Purposes of Patent Extension; RAVICTI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for RAVICTI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA-2013-S-0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus Rm. 3180, Silver Spring, MD 20993, 301-796-7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term

Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product RAVICTI (glycerol phenylbutyrate). RAVICTI is indicated for use as a nitrogen-binding agent for chronic management of adult and pediatric patients 2 years of age or older with urea cycle disorders that cannot be managed by dietary protein restriction

and/or amino acid supplementation alone. Subsequent to this approval, the USPTO received a patent term restoration application for RAVICTI (U.S. Patent No. 5,968,979) from Hyperion Therapeutics, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 2, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of RAVICTI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for RAVICTI is 2,126 days. Of this time, 1,719 days occurred during the testing phase of the regulatory review period, while 407 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* April 10, 2007. The applicant claims April 8, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 10, 2007, when the IND was removed from clinical hold.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 23, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for RAVICTI (NDA 203284) was submitted on December 23, 2011.

3. *The date the application was approved:* February 1, 2013. FDA has verified the applicant's claim that NDA 203284 was approved on February 1, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,450 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by June 16, 2015. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence

during the regulatory review period by October 14, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08845 Filed 4–16–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Addressing Inadequate Information on Important Health Factors in Pharmacoepidemiology Studies Relying on Healthcare Databases; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored by FDA and the University of Maryland Center for Excellence in Regulatory Science and Innovation, entitled “Methodological Considerations to Address Unmeasured Information About Important Health Factors in Pharmacoepidemiology Studies that Rely on Electronic Healthcare Databases to Evaluate the Safety of Regulated Pharmaceutical Products in the Postapproval Setting.” The purpose of the public workshop is to engage in constructive dialogue among regulators, academicians, pharmaceutical industry, clinicians, other stakeholders and the general public on potential strategies to improve

availability of information on important health factors in pharmacoepidemiology studies that rely on electronic healthcare databases to evaluate the safety of pharmaceutical products in the postapproval setting. Electronic healthcare databases are increasingly being used in the postapproval assessment of the safety profile of pharmaceutical drug products.

Date and Time: The public workshop will be held on May 4, 2015, 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Contact Person: Leslie Wheelock, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4345, Silver Spring, MD, 301–796–4580, FAX: 301–847–8106, leslie.wheelock@fda.hhs.gov.

Registration: Submit your online registration information (including name, title, firm name, address, telephone and fax numbers) by April 30, 2015, at: <http://www.pharmacy.umaryland.edu/centers/cersievents/biasinbigdata/>. There is no registration fee for University of Maryland faculty, students, and staff, University of Maryland Center for Excellence in Regulatory Science and Innovation Industrial Consortia Members, and Federal Government employees. There is a \$50.00 registration fee for all other participants. Early registration is recommended because seating is limited. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Leslie Wheelock (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

In many instances, these resources allow for the timely evaluation of drug-related adverse events since data on healthcare utilized by a large number of individuals are readily available. However, because these data are typically collected for administrative purposes, information on important health factors necessary to evaluate drug-outcome relationship may be