nasolabial fold wrinkles in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LAVIV (U.S. Patent No. 5,591,444) from Fibrocell Technologies, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 10, 2012, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of LAVIV represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LAVIV is 3,338 days. Of this time, 2,500 days occurred during the testing phase of the regulatory review period, while 838 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 (21 U.S.C. 355(i)) became effective:* May 3, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 3, 2002.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262*): March 6, 2009. FDA has verified the applicant's claim that the biologics license application (BLA) for LAVIV (BLA 125348) was initially submitted on March 6, 2009.

3. *The date the application was approved:* June 21, 2011. FDA has verified the applicant's claim that BLA 125348 was approved on June 21, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years 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 April 29, 2013. 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 August 27, 2013. 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 petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document. 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: February 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04646 Filed 2–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0169]

Draft Guidance for Industry and Review Staff on Pediatric Information Incorporated Into Human Prescription Drug and Biological Products Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and review staff entitled ''Pediatric Information Incorporated into Human Prescription Drug and Biological Products Labeling.'' This draft guidance is intended to assist applicants and FDA review staff in making decisions about the placement and content of pediatric information in human prescription drug and biological products labeling in accordance with the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), as well as FDA prescription drug and biological product labeling regulations.

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 comment 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 29, 2013.

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. 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.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Matthew Bacho, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6420, Silver Spring, MD 20993–0002, 301–796–0067; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled ''Pediatric Information Incorporated into Human Prescription Drug and Biological Products Labeling.'' In July 2012, FDASIA (Pub. L. 112–144) reauthorized and made permanent the BPCA and PREA. The goal of both the BPCA and PREA is to provide pediatric information in drug labeling to encourage the appropriate use of drugs in treating pediatric patients.

Data submitted in response to a pediatric Written Request under the BPCA and assessments submitted in response to a PREA study requirement must be described in labeling, whether the findings are positive, negative, or inconclusive (sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(a) and 21 U.S.C. 355(c)) as amended by

FDASIA). In addition, when pediatric studies under PREA are fully or partially waived by FDA because there is evidence that a drug would be ineffective or unsafe in a pediatric population or pediatric subpopulation, the safety concern or lack of efficacy must be reflected in the prescription drug labeling (section 505B(a)(4)(D) of the FD&C Act). All useful information on the use of drugs and biological products in the pediatric population should be consistently placed in the proper sections within prescription labeling so that the information is clear and accessible to health care providers.

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 Agency's current thinking on incorporating pediatric information into human prescription drug and biological products labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov*.

Dated: February 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04625 Filed 2–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: The Health Education Assistance Loan (HEAL) Program Regulations (OMB No. 0915–0108)—Extension

Abstract: The Health Education Assistance Loan (HEAL) Program has regulations that contain notification, reporting, and recordkeeping requirements to insure that the lenders and holders participating in the HEAL program follow sound management procedures in the administration of federally-insured student loans. While the regulatory requirements are approved under the OMB number referenced above, much of the burden associated with the regulations is cleared under separate OMB numbers for the HEAL forms and electronic submissions used to report required information. The table below provides the estimate of burden for the remaining regulations.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

REPORTING REQUIREMENTS

Number of respondents	Number of transactions	Total transactions	Hours per response (min)	Total burden hours
13 Holders	4	52	12	10.40
0 Schools	0	0	0	0
Total Reporting				10.40