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.


Leslie Kux,
Assistant Commissioner for Policy.


|||
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 201.56 and 201.57 have been approved under OMB of information in 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


Leslie Kux, Assistant Commissioner for Policy.

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@hsa.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:

<table>
<thead>
<tr>
<th>Reporting Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of respondents</td>
</tr>
<tr>
<td>13 Holders</td>
</tr>
<tr>
<td>0 Schools</td>
</tr>
<tr>
<td>Total Reporting</td>
</tr>
</tbody>
</table>