biologics license application (BLA) for DARZALEX (BLA 761,036) was initially submitted on July 9, 2015.

3. The date the application was approved: November 16, 2015. FDA has verified the applicant’s claim that BLA 761,036 was approved on November 16, 2015.

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 1,000 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see DATES). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see DATES), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition is submitted. (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.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–03342 Filed 2–16–18; 8:45 am]
BILLING CODE 4164–01–P
II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access


Eric D. Hargan
Acting Secretary of Health and Human Services.

[FR Doc. 2018–03402 Filed 2–16–18; 8:45 am]
BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0161]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Food and Drug Administration-Regulated Products: Export Certificates

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 March 22, 2018.

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 emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0498. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Lansdown St., North Bethesda, MD 20852, 301–796–8867, PRAStaff@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.

Export of Food and Drug Administration-Regulated Products: Export Certificates

OMB Control Number 0910–0498—Extension

In April 1996, the FDA Export, Reform, and Enhancement Act of 1996 (FDAREA) (Pub. L. 104–134) amended sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of FDAREA provides that persons exporting certain FDA-regulated products may request FDA to certify that the products meet the requirements of sections 801(e) and 802 or other requirements of the FD&C Act. This section of the law requires FDA to issue certification within 20 days of receipt of the request and to charge firms up to $175 for the certifications. In January 2011, section 801(e)(4)(A) was amended by the FDA Food Safety Modernization Act (Pub. L. 111–353) to provide authorization for export certification fees for food and animal feed.

This section of the FD&C Act authorizes FDA to issue export certificates for regulated food, animal feed, pharmaceuticals, biologics, and devices that are labeled marketed in the United States, as well as for these same products that are not legally marketed but are acceptable to the importing country, as specified in sections 801(e) and 802 of the FD&C Act. FDA has developed various types of certificates that satisfy the requirements of section 801(e)(4)(B) of the FD&C Act. Four of those certificates are discussed in this notice: (1) Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, and (4) Non-Clinical Research Use Only Certificates. FDA has updated the certificates as part of the proposed collection of information to account for the amendment authorizing export certification fees for food and animal feed. Table 1 lists the different certificates and details their uses:

<table>
<thead>
<tr>
<th>Type of certificate</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Supplementary Information Certificate to Foreign Government Requests”.</td>
<td>For the export of products labeled marketed in the United States.</td>
</tr>
<tr>
<td>“Exporter’s Certification Statement Certificate to Foreign Government”</td>
<td>For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&amp;C Act.</td>
</tr>
<tr>
<td>“Supplementary Information Certificate of Exportability Requests”</td>
<td>Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license.</td>
</tr>
<tr>
<td>“Supplementary Information Certificate of a Pharmaceutical Product”</td>
<td>For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the FD&amp;C Act.</td>
</tr>
</tbody>
</table>