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 has been served upon the patent applicant. (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.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03342 Filed 2–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–XXXX]

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs (ORA), Office of Regulatory Science (ORS), and all ORA Laboratories have modified the structure. This new organizational structure was approved by the Secretary of Health and Human Services and effective on June 6, 2016.

FOR FURTHER INFORMATION CONTACT: Paul Norris, DVM, MPA, Director, Office of Regulatory Science, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Food and Drug Administration, NCTR–50 Room 404, Jefferson, Arkansas 72079, Phone: 870–543–4099.

I. Summary

Part D, Chapter D–B (Food and Drug Administration), the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services 35 FR 3685, dated February 25, 1970; 60 FR 56605, dated November 9, 1995; 64 FR 36361, dated July 6, 1999; 72 FR 50112, dated August 30, 2007; 74 FR 41713, dated August 18, 2009; and 76 FR 45270, dated July 28, 2011, is amended to reflect the reorganization of the Office of Regulatory Affairs and the Office of Regulatory Science (ORS), and all ORA Laboratories in this consolidation.

This organization expands current activities in the Office of Regulatory Science and ORA's Laboratories in support of the Agency's Program Alignment Initiative. One of the key elements outlined in the initiative is to transition to distinct commodity-based and vertically integrated regulatory programs with well-defined leads, promoting coherent policy and strategic development. This transforms the regionally organized laboratory system into a true national resource with enhanced ability to meet its public health mission to provide diverse scientific expertise, leadership, and responsive quality analytical services to safeguard public health in a global environment and foster continued flexibility across its functions and programs. It also centralizes and streamlines laboratory operations, scientific research, and support functions into one Office of Regulatory Science. Operationally this facilitates a more efficient and strategic deployment of these resources during public health emergencies and food borne outbreaks. Centralizing the laboratory system greatly enhances command and control of laboratory functions.

The Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs (ORA), Office of Regulatory Science (ORS) has been restructured as follows:

DLLRK. ORGANIZATION. The Office of Regulatory Science is headed by the Director, Office of Regulatory Science and includes the following organizational units:

Office of Regulatory Science (DLLRK)
Automated Laboratory Management Staff (DLLRK1)
Safety and Risk Management Staff (DLLRK2)
Office of Research Coordination and Evaluation (DLLRKA)
Scientific Research Staff (DLLRKA1)
Evaluation Staff (DLLRKA2)
Office of Medical Products, Tobacco, and Specialty Laboratory Operations (DLLRKB)
Medical Products and Tobacco Scientific Staff (DLLRKB1)
Forensic Chemistry Center (DLLRKBA)
Inorganic Branch (DLLRKBA1)
Organic Branch (DLLRKBA2)
Winchester Engineering and Analytical Center (DLLRKBB)
Analytical Branch (DLLRKBB1)
Engineering Branch (DLLRKBB2)
Detroit Laboratory (DLLRKBC)
Northeast Medical Products Laboratory (DLLRKBD)
Pacific Southwest Medical Products Laboratory (DLLRKBE)
Philadelphia Laboratory (DLLRKBF)
San Juan Laboratory (DLLRKBG)
Southeast Tobacco Laboratory (DLLRKBH)
Office of Food and Feed Laboratory Operations (DLLRKC)
Food and Feed Scientific Staff (DLLRKC1)
Arkansas Laboratory (DLLRKCA)
Chemistry Branch I (DLLRKCA1)
Chemistry Branch II (DLLRKCA2)
Microbiology Branch (DLLRKCA3)
Denver Laboratory (DLLRKCB)
Chemistry Branch (DLLRKCB1)
Microbiology Branch (DLLRKCB2)
Kansas City Laboratory (DLLRKCC)
Chemistry Branch I (DLLRKCC1)
Chemistry Branch II (DLLRKCC2)
Northeast Food and Feed Laboratory (DLLRKCD)
Chemistry Branch I (DLLRKCD1)
Chemistry Branch II (DLLRKCD2)
Microbiology Sciences Branch (DLLRKCD3)
Pacific Northwest Laboratory (DLLRKCE)
Chemistry Branch (DLLRKCE1)
Microbiology Branch (DLLRKCE2)
Applied Technology Branch (DLLRKCE3)
San Francisco Laboratory (DLLRKCF)
Chemistry Branch (DLLRKCF1)
Microbiology Branch (DLLRKCF2)
Southeast Food and Feed Laboratory (DLLRKCG)
Microbiology Branch (DLLRKCG1)
Nutrient Analysis Branch (DLLRKCG2)
Chemistry Branch (DLLRKCG3)
Pacific Southwest Food and Feed Laboratory (DLLRKCH)
Chemistry Branch (DLLRKCH1)
Microbiology Branch (DLLRKCH2)

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

Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm*.

Dated: December 21, 2017.

Eric D. Hargan

Acting Secretary of Health and Human Services.

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

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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 Landsdown 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 (FDAERA) (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 FDAERA 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 legally 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 1—CERTIFICATES AND USES

Type of certificate	Use
''Supplementary Information Certificate to Foreign Government Requests''. ''Exporter's Certification Statement Certificate to Foreign Government'' ''Exporter's Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)''.	For the export of products legally marketed in the United States.
''Supplementary Information Certificate of Exportability Requests'' ..... ''Exporter's Certification Statement Certificate of Exportability''	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&C Act.
''Supplementary Information Certificate of a Pharmaceutical Product'' ... ''Exporter's Certification Statement Certificate of a Pharmaceutical Product''.	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.
''Supplementary Information Non-Clinical Research Use Only Certificate''. ''Exporter's Certification Statement (Non-Clinical Research Use Only)''	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&C Act.