from Good Laboratory Practices has been approved under OMB control number 0910–0119. The collection of information resulting from current good manufacturing practices has been approved under OMB control number 0910–0139.

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 either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.regulations.gov*.

Dated: May 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12807 Filed 6–2–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0594]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for XIAFLEX 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 Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological 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, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of U.S. Patents and Trademarks 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 biological 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 biologic product XIAFLEX (collagenase clostridium histolyticum). XIAFLEX is indicated for treatment of adult patients with Dupuytren's contracture with a palpable cord. Subsequent to this approval, the U.S. Patent and Trademark Office received a patent term restoration application for XIAFLEX (U.S. Patent No. RE39941) from Auxilium Pharmaceuticals, Inc., and the U.S. Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 11, 2013, FDA advised the U.S. Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of XIAFLEX represented the first permitted commercial marketing or use of the product. Thereafter, the U.S. Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for XIAFLEX is 5,278 days. Of this time, 4,937 days occurred during the testing phase of the regulatory review period, while 341 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:* August 24, 1995. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 24, 1995.

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*): February 27, 2009. FDA has verified the applicant's claim that the biologics license application (BLA) for XIAFLEX (BLA 125338) was initially submitted on February 27, 2009.

3. *The date the application was approved:* February 2, 2010. FDA has verified the applicant's claim that BLA 125338 was approved on February 2, 2010.

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 1,806 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 August 4, 2014. 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 December 1, 2014. 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: May 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12808 Filed 6–2–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 79 FR 26258–26259 dated May 7, 2014).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice: (1) Establishes the Bureau of Health Workforce (RQ); (2) transfers all functions from the Bureau of Clinician Recruitment and Service (RU) to the newly established Bureau of Health Workforce (RQ); (3) abolishes the Bureau of Clinician Recruitment and Service (RU); (4) transfers all functions from the Bureau of Health Professions (RP) to the newly established Bureau of Health Workforce (RQ); (5) abolishes the Bureau of Health Professions (RP); (6) transfers the Nursing Education Partnership Initiative and Medical Education Partnership Initiative function from the HIV/AIDS Bureau, Office of the Associate Administrator (RV) to the newly established Bureau of Health Workforce (RQ), and; (7) updates the functional statement for the HIV/AIDS Bureau (RV).

Chapter RQ, Bureau of Health Workforce (RQ)

Section RQ, OO Mission

The Bureau of Health Workforce (BHW) improves the health of the nation's underserved communities and vulnerable populations by developing, implementing, evaluating, and refining programs that strengthen the nation's health care workforce. BHW programs holistically support a diverse, culturally competent workforce by addressing components including: Education and training; recruitment and retention; financial support for students, faculty, and practitioners, supporting institutions; data analysis, and evaluation and coordination of global health workforce activities. These efforts support development of a skilled health workforce serving in areas of the nation with the greatest need.

Section RQ–10, Organization

Delete the organization for the Bureau of Clinician Recruitment and Service (RU) and the Bureau of Health Professions (RP) in their entirety and replace with the following: The Bureau of Health Workforce (RQ) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources Services Administration. The Bureau of Health Workforce (RQ) includes the following components:

(1) Office of the Associate Administrator (RQ);

(2) Division of Policy and Shortage Designation (RQ1);

(3) Division of Business Operations (RQ2);

(4) Division of External Affairs (RQ3);

(5) Office of Workforce Development and Analysis (RQA);

(6) Office of Global Health Affairs (RQA1);

(7) Division of Global Training and Development (RQA11);

(8) National Center for Health Workforce Analysis (RQA2);

(9) Division of Medicine and Dentistry (RQA3);

(10) Division of Nursing and Public Health (RQA4);

(11) Division of Practitioner Data Bank (RQA5);

(12) Office of Health Careers (RQB);

(13) Division of Participant Support and Compliance (RQB1);

(14) Division of Health Careers and Financial Support (RQB2);

(15) Division of National Health Service Corps (RQB3); and

(16) Division of Regional Operations (RQB4).

Section RQ–20, Functions

(1) Establish the functional statement for the Bureau of Health Workforce (RQ); (2) delete the functional statement for the Bureau of Clinician and Recruitment and Service (RU) in its entirety and transfer the functions to the newly established Bureau of Health Workforce (RQ); (3) delete the functional statement for the Bureau of Health Professions (RP) in its entirety and transfer the functions to the newly established Bureau of Health Workforce (RQ); (4) transfer the Nursing Education Partnership Initiative (NEPI) and Medical Education Partnership Initiative (MEPI) function from the HIV/AIDS Bureau (RV) to the newly established Bureau of Health Workforce (RQ), and; (5) update the functional statement for the HIV/AIDS Bureau (RV).

Office of the Associate Administrator (RQ)

The Office of the Associate Administrator provides overall leadership, direction, coordination, and planning in support of the BHW's programs designed to help meet the health professions workforce needs of the nation and improve the health of the nation's underserved communities and vulnerable populations. The office guides and directs the bureau's workforce analysis efforts and provides guidance and support for advisory councils. Additionally, the office provides direction by coordinating the recruitment, education, training, and retention of diverse health professionals in the healthcare system and supporting communities' efforts to build more integrated and sustainable systems of care. Specifically: (1) Directs and provides policy guidance for workforce recruitment, student and faculty assistance, training, and placement of health professionals to serve in underserved areas; (2) leads workforce analysis efforts; (3) guides and supports work of advisory councils; (4) provides leadership, and guides bureau programs in recruiting and retaining a diverse workforce; (5) establishes program goals, objectives, and priorities, and provides oversight as to their execution; (6) maintains effective relationships within HRSA and with other federal and nonfederal agencies, state, and local governments, and other public and private organizations concerned with health workforce development and improving access to health care for the nation's underserved; (7) plans, directs, coordinates, and evaluates bureau-wide