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 USPTO 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 PORTRAZZA (necitumumab). PORTRAZZA is indicated, in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer. Subsequent to this approval, the USPTO received a patent term restoration application for PORTRAZZA (U.S. Patent No. 7,598,350) from Eli Lilly and Company, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 30, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of PORTRAZZA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for PORTRAZZA is 2,533 days. Of this time, 2,175 days occurred during the testing phase of the regulatory review period, while 358 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:* December 19, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 19, 2008.

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):* December 2, 2014. The applicant claims October 22, 2014, as the date the biologics license application (BLA) for PORTRAZZA (BLA 125547) was initially submitted. However, FDA records indicate that BLA 125547 was submitted on December 2, 2014.

3. *The date the application was approved:* November 24, 2015. FDA has verified the applicant's claim that BLA 125547 was approved on November 24, 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 1,321 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 *http://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. 2018–03345 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–2016–E–1888]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for DARZALEX 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 the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 23, 2018. 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 20, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 23, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 23, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–E–1888 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; DARZALEX.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

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 product 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 USPTO 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 DARZALEX (daratumumab). DARZALEX is indicated for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent, or who are double-refractory to a proteasome inhibitor and an immunomodulatory agent. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Subsequent to this approval, the USPTO received a patent term restoration application for DARZALEX (U.S. Patent No. 7,829,673) from Genmab A/S, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 25, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of DARZALEX represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for DARZALEX is 1,939 days. Of this time, 1,808 days occurred during the testing phase of the regulatory review period, while 131 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:* July 28, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 28, 2010.

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):* July 9, 2015. FDA has verified the applicant's claim that the

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)