

mg, and 1.25 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for these products, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:**

Bronwen Blass, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6228, Silver Spring, MD 20993-0002, 301-796-5092.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, is the subject of NDA 020992, held by Teva Branded Pharmaceutical Products R&D, Inc. (Teva), and was initially approved

on March 24, 1999. CENESTIN is indicated for treatment of moderate to severe vasomotor symptoms due to menopause and treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause.

In 2016, Teva notified FDA that CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, were being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Foley & Lardner submitted a citizen petition dated March 8, 2017 (Docket No. FDA-2017-P-1461), under 21 CFR 10.30, requesting that the Agency determine whether CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of these products from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to CENESTIN (estrogens, conjugated synthetic A) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 24, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-18376 Filed 8-29-17; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA-2016-E-1283; FDA-2016-E-1291]

**Determination of Regulatory Review Period for Purposes of Patent Extension; KENGREAL**

**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 KENGREAL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 drug product.

**DATES:** Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by October 30, 2017. 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 February 26, 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 October 30, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of October 30, 2017. 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 Nos. FDA-2016-E-1283 and FDA-2016-E-1291 for "Determination of Regulatory Review Period for Purposes of Patent Extension; KENGREAL." 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 Office 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 Office. 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 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 Office, 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 drug products, the testing phase begins when the exemption to permit the clinical

investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product KENGREAL (cangrelor tetrasodium). KENGREAL is indicated as an adjunct to percutaneous coronary intervention for reducing the risk of periprocedural myocardial infarction, repeat coronary revascularization, and stent thrombosis in patients who have not been treated with a P2Y<sub>12</sub> platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor. Subsequent to this approval, the USPTO received patent term restoration applications for KENGREAL (U.S. Patent Nos. 6,114,313 and 6,130,208) from AstraZeneca UK Limited, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of KENGREAL 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 KENGREAL is 6,122 days. Of this time, 5,338 days occurred during the testing phase of the regulatory review period, while 784 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* September 19, 1998. The applicant claims August 20, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 19, 1998, which

was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 30, 2013. FDA has verified the applicant's claim that the new drug application (NDA) for KENGREAL (NDA 204958) was initially submitted on April 30, 2013.

3. *The date the application was approved:* June 22, 2015. FDA has verified the applicant's claim that NDA 204958 was approved on June 22, 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 5 years 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 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 21 CFR 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with 21 CFR 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: August 24, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–18380 Filed 8–29–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

**AGENCY:** Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, notice is hereby given that a meeting is scheduled for the Centers for Disease Control and Prevention (CDC)/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment. This meeting will be open to the public. Information about the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment and the agenda for this meeting can be obtained by contacting CDR Holly Berilla at (301) 443–9965 or [hberilla@hrsa.gov](mailto:hberilla@hrsa.gov).

**DATES:** October 25, 2017, 9:00 a.m. to 5:30 p.m. (Eastern) and October 26, 2017, 9:00 a.m. to 4:15 p.m. (Eastern).

**ADDRESSES:** This meeting will be held in person and offer virtual access through teleconference and Adobe Connect. The address for the meeting is 5600 Fishers Lane, Pavilion, Rockville, Maryland 20857. The conference call-in number is (888) 469–0566 and passcode is 6012320. The webinar link is [https://hrsa.connectsolutions.com/october\\_chac\\_meeting/](https://hrsa.connectsolutions.com/october_chac_meeting/).

#### FOR FURTHER INFORMATION CONTACT:

Those requesting information regarding the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment should contact CDR Holly Berilla, Senior Public Health Analyst, Division of Policy and Data (DPD), HIV/AIDS Bureau (HAB), HRSA, in one of three ways: (1) Mail a request to CDR Holly Berilla, Senior Public Health Analyst, HRSA/HAB/DPD, 5600 Fishers Lane, 9N164C, Rockville, Maryland 20857; (2) call (301) 443–9965; or (3) send an email to [hberilla@hrsa.gov](mailto:hberilla@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** The CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment was established under Section 222 of the Public Health Service Act, [42 U.S.C. Section 217a], as amended.

The purpose of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment is to advise the Secretary of

HHS, the Director of CDC, and the Administrator of HRSA regarding objectives, strategies, policies, and priorities for HIV, viral hepatitis, and other STDs; prevention and treatment efforts including surveillance of HIV infection, AIDS, viral hepatitis and other STDs, and related behaviors; epidemiologic, behavioral, health services, and laboratory research on HIV/AIDS, viral hepatitis, and other STDs; identification of policy issues related to HIV/viral hepatitis/STD professional education, patient healthcare delivery, and prevention services; HHS policies about prevention of HIV/AIDS, viral hepatitis and other STDs; treatment, healthcare delivery, and research and training; strategic issues influencing the ability of CDC and HRSA to fulfill their missions of providing prevention and treatment services; programmatic efforts to prevent and treat HIV, viral hepatitis, and other STDs; and support to CDC and HRSA in their development of responses to emerging health needs related to HIV, viral hepatitis, and other STDs.

During the October 25 to 26, 2017, meeting, the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment will discuss strategies to link, retain, and re-engage people living with HIV into the Ryan White HIV/AIDS Program system of care; HAB's benchmarking and risk adjustment initiatives; HRSA and CDC initiatives regarding congenital syphilis; and committee workgroup reports. Agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment should be sent to CDR Holly Berilla, using the contact information listed above, by October 11, 2017.

The building at 5600 Fishers Lane, Rockville, MD 20857, requires a security screening on entry. To facilitate your access to the building please contact CDR Holly Berilla (contact information provided above). Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify CDR Holly Berilla (contact information provided above) at least 10 days prior to the meeting.