Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA approved VIOXX (rofecoxib) Tablets (NDA 21042 and NDA 21647) and VIOXX (rofecoxib) Suspension (NDA 21052) for the following indications:

- For relief of the signs and symptoms of osteoarthritis.
- For relief of the signs and symptoms of rheumatoid arthritis in adults.
- For relief of the signs and symptoms of pauciarticular or polyarticular course juvenile rheumatoid arthritis in patients 2 years and older and who weigh 10 kg (22 lbs) or more.
- For the management of acute pain in adults.
- For the treatment of primary dysmenorrhea.
- For the acute treatment of migraine attacks with or without aura in adults.

On September 27, 2004, Merck informed the Agency it had halted the Adenomatous Polyp Prevention on VIOXX (APPROVe) trial due to an increased relative risk for confirmed cardiovascular events, such as heart attack and stroke, beginning after 18 months of treatment in patients taking VIOXX (rofecoxib) compared to those taking placebo. On September 30, 2004, Merck voluntarily withdrew VIOXX from the U.S. market. In early 2005, FDA conducted a comprehensive review of the approved cyclooxygenase-2 (COX–2) selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs) and the risk of adverse cardiovascular events. On April 6, 2005, after holding a joint meeting of the Arthritis and Drug Safety and Risk Management Advisory Committees, FDA issued a decisional memorandum summarizing the Agency's analysis and recommendations regarding the NSAIDs that were the subject of the review (*https://www.fda.gov/media/74279/download*). In that report, FDA made various recommendations, including modifications to the safety information in the labeling of approved COX–2 selective NSAIDs, including VIOXX. On June 3, 2005, Merck subsequently requested FDA's input on the content of potential supplemental NDAs to support labeling changes, in the event that Merck decided to bring the drug back to the U.S. market. On December 12, 2005, FDA identified certain safety analyses and other information that would be required in support of such supplemental NDAs.

In Merck's letter requesting withdrawal of VIOXX, Merck summarized its views of the reasons for withdrawal of approval as follows. Merck ultimately made a business decision not to recommence distribution of VIOXX in the United States and, therefore, did not conduct the additional analyses or submit supplemental NDAs supporting the reintroduction of VIOXX. In light of the company's commercial decision not to reintroduce VIOXX to the U.S. market, Merck has requested that FDA withdraw approval of NDA 21042, NDA 21052, and NDA 21647 for VIOXX tablets and suspension.

FDA has determined that withdrawal of these NDAs under § 314.150(d) (21 CFR 314.150(d)) is appropriate, because Merck did not provide the additional information necessary to reintroduce VIOXX (rofecoxib) to the U.S. market that FDA requested in its December 12, 2005, correspondence. On October 7, 2021, Merck requested that FDA withdraw approval of NDA 21042, NDA 21052, and NDA 21647 for VIOXX (rofecoxib) under § 314.150(d) and waived its opportunity for a hearing.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 21042 and NDA 21647 for VIOXX (rofecoxib) Tablets, 12.5 mg, 25 mg, and 50 mg, and NDA 21052 for VIOXX (rofecoxib) Suspension, 12.5 mg/5 mL and 25 mg/5 mL, and all amendments and supplements thereto, are withdrawn under § 314.150(d). Distribution of VIOXX (rofecoxib) Tablets, 12.5 mg, 25 mg, and 50 mg, and VIOXX (rofecoxib) Suspension, 12.5 mg/5 mL and 25 mg/5 mL, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: September 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19740 Filed 9–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–2255; FDA–2020–E–2256; and FDA–2020–E–2254]

Determination of Regulatory Review Period for Purposes of Patent Extension; BULKAMID URETHRAL BULKING SYSTEM

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 BULKAMID URETHRAL BULKING SYSTEM 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 medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by November 14, 2022. 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 March 13, 2023. 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. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 14, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2020–E–2255; FDA–2020–E–2256; and FDA–2020–E–2254 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; BULKAMID URETHRAL BULKING SYSTEM.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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 numbers, 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, 240–402–7500.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device BULKAMID URETHRAL BULKING SYSTEM. The BULKAMID URETHRAL BULKING SYSTEM is indicated for urethral injection for the treatment of stress urinary incontinence (SUI) due to intrinsic sphincter deficiency in adult women who have SUI or stress predominant mixed incontinence. Subsequent to this approval, the USPTO received patent term restoration applications for BULKAMID URETHRAL BULKING SYSTEM (U.S. Patent Nos. 7,678,146; 7,758,497; and 7,780,958) from Contura A/S, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated March 1, 2021, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of the BULKAMID URETHRAL BULKING SYSTEM 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 the BULKAMID URETHRAL BULKING SYSTEM is 4,529 days. Of this time, 3,617 days occurred during the testing phase of the regulatory review period, while 912 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* September 6, 2007. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on January 18, 2008. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on September 6, 2007, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* July 31, 2017. FDA has verified the applicant's claim that the premarket approval application

(PMA) for BULKAMID URETHRAL BULKING SYSTEM (PMA P170023) was initially submitted July 31, 2017.

3. *The date the application was approved:* January 28, 2020. FDA has verified the applicant's claim that PMA P170023 was approved on January 28, 2020.

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 applications 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 § 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: September 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19723 Filed 9–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1908]

Policy for Monkeypox Tests To Address the Public Health Emergency; Guidance for Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Policy for Monkeypox Tests To Address the Public Health Emergency.'' On August 4, 2022, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency related to monkeypox. Monkeypox virus is a zoonotic infection (a virus transmitted to humans from animals), caused by *Orthopoxvirus* genus of the *Poxviridae* family similar to variola virus (the causative agent of smallpox), and can spread to humans. Since early May 2022, cases of monkeypox have been reported from countries where the disease is not endemic and continue to be reported in several endemic countries. Rapid detection of monkeypox cases in the United States requires wide availability of diagnostic testing to control the emergence of this contagious infection. This guidance describes FDA's review priorities of emergency use authorization (EUA) requests for monkeypox diagnostic tests, as well as FDA's enforcement policies for various monkeypox tests. The guidance document has been implemented without prior comment, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on September 13, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2022–D–1908 for ''Policy for Monkeypox Tests To Address the Public Health Emergency.'' Received comments 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, 240–402–7500.

- 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