As part of these ongoing efforts, medical device manufacturers have expressed a desire for greater clarity regarding the Agency's expectations for software validation for computers and automated data processing systems used as part of production or the quality system. Given the rapidly changing nature of software, manufacturers have also expressed a desire for a more iterative, agile approach for validation of computer software used as part of production or the quality system.

Traditionally, software validation has often been accomplished via software testing and other verification activities conducted at each stage of the software development lifecycle. However, software testing alone is often insufficient to establish confidence that the software is fit for its intended use. FDA believes that applying a risk-based approach to computer software used as part of production or the quality system would better focus manufacturers' assurance activities to help ensure product quality while helping to fulfill the validation requirements of § 820.70(i). For these reasons, FDA is providing recommendations on computer software assurance for computers and automated data processing systems used as part of medical device production or the quality system. FDA believes that these recommendations will help foster the adoption and use of innovative technologies that promote patient access to high-quality medical devices and help manufacturers to keep pace with the dynamic, rapidly changing technology landscape, while promoting compliance with laws and regulations implemented by FDA. FDA invites comments on the computer software assurance framework outlined in this guidance, including any comments or questions regarding the application of 21 CFR part 11 to requirements arising under § 820.70(i) with respect to computers or automated data processing systems used as part of production or the quality system.

When final, this guidance will supplement FDA's guidance, ''General Principles of Software Validation'' (''Software Validation guidance'') (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-principles-software-validation*), except this guidance will supersede Section 6 (''Validation of Automated Process Equipment and Quality System Software'') of the Software Validation guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Computer Software Assurance for Production and Quality System Software. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products*. This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics*. Persons unable to download an electronic copy of ''Computer Software Assurance for Production and Quality System Software'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17045 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
11	Electronic records; Electronic signatures	0910–0303
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: September 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19763 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–N–1999]

Merck Sharp & Dohme Corp.; Withdrawal of Approval of New Drug Applications for VIOXX (Rofecoxib) Tablets and Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug applications (NDAs) for VIOXX (rofecoxib) Tablets, 12.5 milligrams (mg), 25 mg, and 50 mg, and VIOXX (rofecoxib) Suspension, 12.5 mg/5 milliliter (mL) and 25 mg/5 mL, held by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., P.O. Box 100, 1 Merck Dr., Whitehouse Station, NJ 08889 (Merck). Merck has voluntarily requested that FDA withdraw approval of these applications and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of September 13, 2022.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and

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