locate information, whether information was located, and the type(s) of information returned to the requesting entity, are archived once a year based on the fiscal year. The records are retained for two completed fiscal years and then destroyed. These records indicate the type of information located for the authorized user, not the information itself.

(3) Match results generated as a result of FCR-to-FCR comparisons which locate individuals who are participants in child support cases or orders in more than one state are transmitted to the relevant states. Copies of FCR-to-FCR match results are retained for 60 days and then deleted.

(4) Any record relating or potentially relating to a fraud or abuse investigation or a pending or ongoing legal action, including a class action, is retained until conclusion of the investigation or legal action.

(5) Copies of the FCR records transmitted to the Secretary of the Treasury for the purpose of administering sections of the Internal Revenue Code which grant tax benefits based on support or residence of children (routine use 8) are retained for one year and then deleted.

(6) Records collected or disseminated for technical assistance to child support agencies or other authorized agencies or entities are retained for 60 days to five years, and audit data is retained for a period of up to two years.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The system leverages cloud service providers that maintain an authority to operate in accordance with applicable laws, rules, and policies, including Federal Risk and Authorization Management Program (FedRAMP) requirements. Specific administrative, technical, and physical controls are in place to ensure that the records collected and maintained in the FCR are secure from unauthorized access. Access to the records is restricted to authorized personnel who are advised of the confidentiality of the records and the civil and criminal penalties for misuse and who sign a nondisclosure oath to that effect. Personnel are provided privacy and security training before being granted access to the records and annually thereafter. Logical access controls are in place to limit access to the records to authorized personnel and to prevent browsing. The records are processed and stored in a secure environment. All records are stored in an area that is physically safe from access by unauthorized persons at all times.

Safeguards conform to the HHS Information Security and Privacy Program, which may be found at *https://www.hhs.gov/ocio/securityprivacy/index.html.*

RECORD ACCESS PROCEDURES:

To request access to a record about you, submit a written request to the System Manager, in accordance with the Department's Privacy Act implementation regulations in 45 CFR. The request should include your name, telephone number and/or email address, current address, and signature, and sufficient particulars (such as, date of birth or SSN) to enable the System Manager to distinguish between records on subject individuals with the same name. To verify your identity, your signature must be notarized or your request must include your signed, written certification that you are the individual who you claim to be and that you understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000.

CONTESTING RECORD PROCEDURES:

To request correction of a record about you in this system of records, submit a written amendment request to the System Manager, in accordance with the Department's Privacy Act implementation regulations in 45 CFR. The request must contain the same information required for an access request and include verification of your identity in the same manner required for an access request. In addition, the request must reasonably identify the record and specify the information contested; the corrective action sought; and the reasons for requesting the correction; and should include supporting justification or documentation to show how the record is inaccurate, incomplete, untimely, or irrelevant.

NOTIFICATION PROCEDURES:

To find out if this system of records contains a record about you, submit a written notification request to the System Manager, in accordance with the Department's Privacy Act implementation regulations in 45 CFR. The request must identify this system of records, contain the same information required for an access request, and include verification of your identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

A notice of proposed rulemaking has been published to add this system of records to the list of exempt systems of records in HHS regulations implementing the Privacy Act (45 CFR 5b, at 5b.11), and that exemption will be effective upon publication of a Final Rule. The Final Rule will, pursuant to 5 U.S.C. 552a(k)(2), exempt case files marked with the Family Violence Indicator (FVI), which constitute investigatory material compiled for law enforcement purposes, from the accounting, access, and amendment requirements in subsections (c)(3) and (d)(1) through (4) of the Privacy Act (5 U.S.C. 552a(c)(3) and (d)(1) through (4)), subject to the limitation set forth in subsection (k)(2).

With respect to case files marked ''FVI,'' the exemption is intended to be consistent with the disclosure prohibition in section 453(b)(2) of the Social Security Act (42 U.S.C. 653(b)(2)) which prohibits disclosure of case records containing reasonable evidence of domestic violence or child abuse, disclosure of which could be harmful to the custodial parent or the child of such parent, to anyone other than a court or an agent of the court. See also 45 CFR 303.21(e) (describing safeguarding requirements for records marked with the FVI).

HISTORY:

80 FR 17912 (Apr. 2, 2015), updated 83 FR 6591 (Feb. 14, 2018).

[FR Doc. 2022–19851 Filed 9–12–22; 8:45 am]

BILLING CODE 4184–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0795]

Computer Software Assurance for Production and Quality System Software; Draft Guidance for Industry 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 the draft guidance entitled ''Computer Software Assurance for Production and Quality System Software.'' FDA is issuing this draft guidance to provide 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. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 14, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–0795 for ''Computer Software Assurance for Production and Quality System Software.'' 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 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 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 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Computer Software Assurance for Production and Quality System Software'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Francisco Vicenty, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1534, Silver Spring, MD 20993–0002, 301–796–5577; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA envisions a future state where the medical device ecosystem is inherently focused on device features and manufacturing practices that promote product quality and patient safety. FDA has sought to identify and promote successful manufacturing practices and help device manufacturers raise their manufacturing quality level. In doing so, one goal is to help manufacturers produce high-quality medical devices that align with the laws and regulations implemented by FDA. Compliance with the Quality System regulation, 21 CFR part 820, is required for manufacturers of finished medical devices to the extent they engage in operations to which part 820 applies. Recommending best practices should promote product quality and patient safety, and correlate to higher-quality outcomes. This draft guidance addresses practices relating to computers and automated data processing systems used as part of production or the quality system.

FDA recognizes the potential for advances in manufacturing technologies, including the adoption of automation, robotics, simulation, and other digital capabilities, to provide significant benefits for enhancing the quality, availability, and safety of medical devices. FDA has engaged with stakeholders to keep abreast of the latest technologies and to better understand stakeholders' challenges and opportunities for further advancement.

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