DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2796]

Bristol Myers Products Inc.; Withdrawal of Approval of a New Drug Application for BUFFERIN (Aspirin) Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of a new drug application (NDA) for BUFFERIN (aspirin) tablets. The basis for the withdrawal is that the holder of the NDA has repeatedly failed to file required annual reports for this NDA.

DATES: Approval is withdrawn as of July 21, 2023.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–348–3035, *Jennifer.Forde@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with § 314.81 (21 CFR 314.81). In the **Federal Register** of November 23, 2022 (87 FR 71652), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of NDA 006499 for BUFFERIN (aspirin) tablets, and all amendments and supplements thereto, on the grounds that the holder of NDA 006499 has repeatedly failed to file required annual reports for this NDA.

NDA 006499 for BUFFERIN (aspirin) tablets became effective on June 30, 1948. The holder of NDA 006499 is currently identified in FDA's records as Bristol Myers Products Inc. The Agency has received conflicting information regarding the identity of the current NDA holder. However, to change the holder of record, information specified in § 314.72 (21 CFR 314.72) must be provided to the Agency. Since the time that the holder of record was identified as Bristol Myers Products Inc., the Agency has not received change of application ownership information that would satisfy the requirements of § 314.72. The Agency therefore identified Bristol Myers Products Inc. as the NDA holder of record in the NOOH published in the **Federal Register** of November 23, 2022, but if another entity held NDA 006499, the Agency also provided notice to that entity through the same NOOH.

Bristol Myers Products Inc. did not respond to the NOOH and nor did any other party. Failure of the NDA holder to file a written notice of participation and request for hearing pursuant to § 314.200 (21 CFR 314.200) constitutes an election by the holder of the NDA not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of its NDA and a waiver of any contentions concerning the legal status of the drug product.

FDA finds that the holder of NDA 006499 has repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, FDA finds that the holder of the NDA 006499 has waived the opportunity for a hearing concerning the withdrawal of approval of this NDA as well as any contentions concerning the legal status of the drug product covered by this NDA. Therefore, under these findings, approval of NDA 006499 and all amendments and supplements thereto is hereby withdrawn as of July 21, 2023.

Based on information available to the Agency, it appears that the product covered by NDA 006499 has not been marketed for many years and another buffered aspirin drug product, using the same trade name ''BUFFERIN'' but with a different formulation, is currently being marketed as an over the counter (OTC) monograph drug. The marketing of this current ''BUFFERIN'' product is subject to the requirements for legal marketing of OTC monograph drugs under section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h). Withdrawal of the approval of NDA 006499 does not impact nonprescription aspirin products that are legally marketed without an approved application as OTC monograph drugs in accordance with section 505G of the FD&C Act, including conforming to applicable conditions of use specified in OTC Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use (See OTC *Monographs@FDA* web page available at *https://www.accessdata.fda.gov/scripts/cder/omuf/?event=reqOrders*).

Dated: July 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15454 Filed 7–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0601]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 21, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0152. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice Regulations for Medicated Feeds—21 CFR Part 225

OMB Control Number 0910–0152—Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (CGMP) regulations for drugs, including medicated feeds. Medicated feeds are