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DATES: Approval is withdrawn as of July 21, 2023.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

administered to animals for the prevention, cure, mitigation, or treatment of disease, or growth promotion and feed efficiency. Statutory requirements for CGMPs have been codified under part 225 (21 CFR part 225). Medicated feeds that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the FD&C Act. Under part 225, a manufacturer is required to establish, maintain, and retain records for a medicated feed, including records to document procedures required during the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (*i.e.,* batch and stability testing), labels, and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of medicated feeds to investigate violative drug residues in products from treated animals and to investigate product defects when a drug is recalled. In addition, FDA will use the CGMP criteria in part 225 to determine whether the systems and procedures used by manufacturers of medicated feeds are adequate to ensure that their feeds meet the requirements of the FD&C Act as to safety, and also that they meet their claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act.

A license is required when the manufacturer of a medicated feed involves the use of a drug or drugs that FDA has determined requires more control because of the need for a withdrawal period before slaughter or because of carcinogenic concerns. Conversely, a license is not required, and the recordkeeping requirements are less demanding, for those medicated feeds for which FDA has determined that the drugs used in their manufacture need less control. Respondents to this collection of information are commercial feed mills and mixers/feeders.

In the **Federal Register** of February 6, 2023 (88 FR 7741), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN

[Registered licensed commercial feed mills] [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
225.42(b)(5) through (8) requires records of receipt, storage, and inventory control of medicated feeds.	791	260	205,660	1	205,660
225.58(c) and (d) requires records of the results of periodic assays for medicated feeds that are in accord with label specifications and also those medicated feeds not within documented permissible assay limits.	791	45	35,595	0.5 (30 minutes)	17,798
225.80(b)(2) requires that verified medicated feed label(s) be kept for 1 year	791	1,600	1,265,600	0.12 (7 minutes)	151,872
225.102(b)(1) through (5), requires records of master record files and production records for medicated feeds.	791	7,800	6,169,800	0.08 (5 minutes)	493,584
225.110(b)(1) and (2) requires maintenance of distribution records for medicated feeds.	791	7,800	6,169,800	0.02 (1 minute)	123,396
225.115(b)(1) and (2) requires maintenance of complaint files by the medicated feed manufacturer.	791	5	3,955	0.12 (7 minutes)	475
Total					992,785

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

[Registered licensed mixer/feeders] [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
225.42(b)(5) through (8) requires records of receipt, storage, and inventory control of medicated feeds.	100	260	26,000	0.15 (9 minutes)	3,900
225.58(c) and (d) requires records of the results of periodic assays for medicated feeds that are in accord with label specifications and also those medicated feeds not within documented permissible assay limits.	100	36	3,600	0.5 (30 minutes)	1,800
225.80(b)(2) requires that verified medicated feed label(s) be kept for 1 year	100	48	4,800	0.12 (7 minutes)	576
225.102(b)(1) through (5) requires records of master record files and production records for medicated feeds.	100	260	26,000	0.4 (24 minutes)	10,400
Total					16,676

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN

[Nonregistered non-licensed commercial feed mills] [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
225.142 requires procedures for identification, storage, and inventory control (receipt and use) of Type A medicated articles and Type B medicated feeds.	4,357	4	17,428	1	17,428

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued
[Nonregistered non-licensed commercial feed mills] [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
225.158 requires records of investigation and corrective action when the results of laboratory assays of drug components indicate that the medicated feed is not in accord with the permissible assay limits.	4,357	1	4,357	4	17,428
225.180 requires identification, storage, and inventory control of labeling in a manner that prevents label mix-ups and assures that correct labels are used for medicated feeds.	4,357	96	418,272	0.12 (7 minutes)	50,193
225.202 requires records of formulation, production, and distribution of medicated feeds.	4,357	260	1,132,820	0.65 (39 minutes)	736,333
Total					821,382

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN
[Nonregistered non-licensed mixer/feeders] [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
225.142 requires procedures for identification, storage, and inventory control (receipt and use) of Type A medicated articles and Type B medicated feeds.	3,400	4	13,600	1	13,600
225.158 requires records of investigation and corrective action when the results of laboratory assays of drug components indicate that the medicated feed is not in accord with the permissible assay limits.	3,400	1	3,400	4	13,600
225.180 requires identification, storage, and inventory control of labeling in a manner that prevents label mix-ups and assures that correct labels are used for medicated feeds.	3,400	32	108,800	0.12 (7 minutes)	13,056
225.202 requires records of formulation, production, and distribution of medicated feeds.	3,400	260	884,000	0.33 (20 minutes)	291,720
Total					331,976

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall decrease of 10,435 hours and an increase of 831,545 records since the last OMB approval. We attribute this adjustment due to an increase in the number of non-registered, non-licensed commercial medicated feed mills and decrease in non-licensed medicated feed mill recordkeeping the last few years.

Dated: July 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15487 Filed 7–20–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0343]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice for Blood and Blood Components and Reducing the Risk of Transfusion-Transmitted Infections

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) 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 0910–0116. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.