EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility and Registration Form	100	1	5/60	8
Data Use Agreement	100	1	3/60	5
ASC Site Information Form	100	1	5/60	8
Data Files Submission	100	1	1	100
Total	NA	NA	NA	121

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents/POCs	Total burden hours	Average hourly wage rate *	Total cost burden
Eligibility and Registration Form	100	8	$47.97	$383.76
Data Use Agreement	100	5	47.97	239.85
ASC Site Information	100	8	47.97	383.76
Data Files Submission	100	100	47.97	4,797.00
Total	NA	121	NA	5,804.37

* Based on the mean hourly wage for 100 ASC Administrative Services Managers (11–3010; $47.97) obtained from the May 2019 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 621400—Outpatient Care Centers (located at *https://www.bls.gov/oes/current/naics4_621400.htm#11-00000*).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: May 19, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–10938 Filed 5–24–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–P–2048]

Determination That MANGANESE SULFATE, Injectable, Equivalent 0.1 Milligram Manganese/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that MANGANESE SULFATE, injectable, equivalent (Eq) 0.1 milligram (mg) manganese/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for MANGANESE SULFATE, injectable, Eq 0.1 mg manganese/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 240–402–9674, *Sungjoon.Chi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the

listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

MANGANESE SULFATE, injectable, Eq 0.1 mg manganese/mL, is the subject of NDA 019228, held by Abraxis Pharmaceutical Products, and initially approved on May 5, 1987. MANGANESE SULFATE is indicated for use as a supplement to intravenous solutions given for total parenteral nutrition. Administration helps to maintain manganese serum levels and to prevent depletion of endogenous stores and subsequent deficiency symptoms.

MANGANESE SULFATE, injectable, Eq 0.1 mg manganese/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Fresenius Kabi USA, LLC, submitted a citizen petition dated October 4, 2020 (Docket No. FDA–2020–P–2048), under 21 CFR 10.30, requesting that the Agency determine whether MANGANESE SULFATE, injectable, Eq 0.1 mg manganese/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that MANGANESE SULFATE, injectable, Eq 0.1 mg manganese/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MANGANESE SULFATE, injectable, Eq 0.1 mg manganese/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MANGANESE SULFATE, injectable, Eq 0.1 mg manganese/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MANGANESE SULFATE, injectable, Eq 0.1 mg manganese/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to MANGANESE SULFATE, injectable, Eq 0.1 mg manganese/mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 18, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11021 Filed 5–24–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4751]

FDA Reauthorization Act Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs; Guidance for Industry; 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 for industry entitled ''FDARA Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs.'' This guidance addresses early planning for pediatric evaluation of certain molecularly targeted oncology drugs, including biological products, for which original new drug applications (NDAs) and biologics license applications (BLAs) are expected to be submitted to FDA, in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the FDA Reauthorization Act of 2017 (FDARA). Early pediatric evaluation of certain molecularly targeted oncology drugs as required by the FD&C Act is expected to accelerate the creation of an informed pediatric development plan and ultimately the development of promising drugs for pediatric patients. This guidance finalizes the draft guidance entitled ''FDARA Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs'' issued on December 13, 2019, and finalizes certain material related to implementation of FDARA that was included in the draft guidance entitled ''Pediatric Study Plans for Oncology Drugs: Questions and Answers'' issued on January 16, 2020. Accordingly, FDA does not intend to finalize the draft guidance entitled ''Pediatric Study Plans for Oncology Drugs: Questions and Answers,'' which is now withdrawn.

DATES: The announcement of the guidance is published in the **Federal Register** on May 25, 2021.

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–2019–D–4751 for ''FDARA Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs.'' 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