ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
TANF Financial Report, Form ACF–196T	51	4	1.5	306

Estimated Total Annual Burden Hours: 306.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Social Security Act, Section 409; 45 CFR 286,245–286.285.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–23013 Filed 10–21–22; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5553]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Annual Summary Reporting Requirements Under the Right to Try Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 November 23, 2022.

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 0910–0893. 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.

Annual Summary Reporting Requirements Under the Right to Try Act

OMB Control Number 0910–0893

This information collection helps to implement provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by the Right to Try Act, which requires sponsors and manufacturers who provide an ''eligible investigational drug'' under the Right to Try Act to submit to FDA an annual summary of such use. Regulations under § 300.200 (21 CFR 300.200) will require that sponsors and manufacturers submit to FDA an annual summary no later than March 31 of each year, including data for the preceding calendar year, that includes the following data elements:

- The name of the eligible investigational drug and applicable investigational new drug application number.
- The number of doses supplied to the eligible patient.
- The number of eligible patients treated.
- The use for which the eligible investigational drug was made available to the eligible patient.
- Any known serious adverse events and outcomes that the eligible patient treated with an eligible investigational drug experienced.

Description of Respondents: Respondents to the information collection are sponsors and manufacturers who provide an eligible investigational drug to eligible patients in accordance with the Right to Try Act and will submit to FDA annual summaries.

In the **Federal Register** of September 14, 2022 (87 FR 56269), we published a final rule (RIN 0910–AI36), including an analysis of the information collection, and discussed the development of an associated form to facilitate submission of the requisite information. Accordingly, we have developed Form FDA 5023 entitled ''Right To Try Reporting Requirement: Annual Summary,'' which is currently available in the docket for comment purposes only, and we are inviting public comment. As required by the applicable statute, section 561B of the FD&C Act (21 U.S.C. 360bbb–0a), the information is submitted to an FDA-designated point of contact, and in accordance with instructions to be posted at: *https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try.*

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR citation	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Sponsors and manufacturers submit annual summaries in accordance with the Right to Try Act (§ 300.200) using Form FDA 5023	6	1	6	2.5	15

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

Consistent with estimates in our Final Regulatory Impact Analysis for the associated final rule, we estimate that six sponsors and manufacturers will prepare and submit Form FDA 5023 and assume it takes 2.5 hours to prepare and submit each summary, which results in a total of 15 hours annually.

Dated: October 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23035 Filed 10–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2391]

Miles Laboratories Inc.; Proposal To Withdraw Approval of an Abbreviated New Drug Application for Alcohol and Dextrose Injection; 5 Milliliters/100 Milliliters, 5 Grams/100 Milliliters; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of an abbreviated new drug application (ANDA) for Alcohol and Dextrose Injection, 5 milliliters (mL)/100 mL, 5 grams (g)/100 mL, and is announcing an opportunity for the ANDA holder to request a hearing on this proposal: Miles Laboratories Inc., P.O. Box 1986, 4th and Parker St., Berkeley, CA 94701, is the last holder of record. The bases for the proposal are that the ANDA holder has repeatedly failed to file required annual reports for this ANDA and that the Agency has scientific data and experience to show that the drug product under this ANDA is unsafe for use under the conditions of use for which the product was approved.

DATES: The ANDA holder may submit a request for a hearing by November 23, 2022. Submit all data, information, and analyses upon which the request for a hearing relies by December 23, 2022. Submit electronic or written comments by December 23, 2022.

ADDRESSES: The request for a hearing may be submitted by the ANDA holder by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to *https://www.regulations.gov,* including any attachments to the request for a hearing, will be posted to the docket unchanged.

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.
- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request 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. The request for a hearing must include the Docket No. FDA–2022–N–2391 for ''Miles Laboratories Inc.; Proposal To Withdraw Approval of an Abbreviated New Drug Application for Alcohol and Dextrose Injection, 5 Milliliters/100 Milliliters, 5 Grams/100 Milliliters; Opportunity for a Hearing.'' The request for a hearing will be placed in the docket and 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.

The ANDA holder may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- Confidential Submissions—To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. 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 any decisions on this matter. 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* or available at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law.

Comments Submitted by Other Interested Parties: For all comments submitted by other interested parties, submit comments 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