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

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–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.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 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.

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993–0002, 301–796–1546.

SUPPLEMENTARY INFORMATION: On November 22, 1974, FDA approved ANDA 083483 for Alcohol and Dextrose Injection. In a letter dated June 23, 1999, Bayer Corporation, which had at least partially acquired Miles Laboratories Inc., notified FDA that Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, the subject of ANDA 083483, was no longer marketed, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' FDA has not received information specified in 21 CFR 314.72 to change the ownership of ANDA 083483, although Miles Laboratories Inc. does not appear to be separately manufacturing drug products. The Agency is therefore identifying Miles Laboratories Inc. as the ANDA holder of record in this **Federal Register** notice, but in the event that another entity holds ANDA 083483, the Agency is also providing notice to that entity.

The holder of an approved ANDA to market a new drug for human use is required to submit annual reports to FDA concerning its approved ANDA under §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). Because the holder of ANDA 083483 for Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, has repeatedly failed to submit the required annual reports, FDA proposes to withdraw approval of ANDA 083483 under § 314.150(b)(1) (21 CFR 314.150(b)(1)).

Additionally, under 21 CFR 314.161, FDA has determined that Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, approved under ANDA 083483 was withdrawn from sale for safety and effectiveness reasons (see 86 FR 72606 (December 22, 2021)) (this determination also applied to other applications and to the 10 mL/100 mL, 5 g/100 mL strength of Alcohol and Dextrose Injection approved under NDA 004589). In light of our determination, FDA proposes to withdraw approval of ANDA 083483 under § 314.150(a)(2)(i) because the Agency has scientific data and experience to show that Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, is unsafe for use under the conditions of use for which the product was approved.

As explained in our **Federal Register** notice determining that Alcohol and Dextrose was withdrawn for safety and effectiveness reasons, Alcohol and Dextrose Injection is indicated to provide increased caloric intake. The use of Alcohol and Dextrose raises several safety concerns because there are many risks associated with the exposure to alcohol. Today, alcohol is contraindicated for use in patients with neurologic disorders, such as seizures, who have current or past substance abuse problems or who are pregnant. It can cause intoxication, respiratory depression, and disturbances in serum glucose levels. FDA-approved alternatives for intravenous calorie supplementation that do not include alcohol were approved after these Alcohol and Dextrose products and are available today.

Therefore, notice is given to the ANDA holder and to all other interested persons that the Director of CDER proposes to issue an order, under section 505(e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)(2)), withdrawing approval of ANDA 083483 and all amendments and supplements thereto on the grounds that: (1) the ANDA holder has failed to submit reports required under §§ 314.81 and 314.98 and section 505(k) of the FD&C Act, and (2) the Agency has scientific data and experience to show that Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, is unsafe for use under the conditions of use for which the product was approved.

In accordance with section 505(e) of the FD&C Act and §§ 314.150(a)(2)(i) and (b)(1) and § 314.200 (21 CFR 314.200), the ANDA holder is hereby provided an opportunity for a hearing to show why the approval of ANDA 083483 should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the

legal status of the drug product covered by ANDA 083483.

An ANDA holder who decides to seek a hearing must file the following: (1) a written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an ANDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that ANDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the ANDA and constitutes a waiver of any contentions concerning the legal status of the drug product. FDA will then withdraw approval of the ANDA, and the drug product may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved ANDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing (§ 314.200(g)). If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing (§ 314.200(g)(1)).

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: October 14, 2022.

Patrizia Cavazzoni,

Acting Director, Center for Drug Evaluation and Research.

[FR Doc. 2022–23034 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–D–2170]

Topical Dermatologic Corticosteroids: In Vivo Bioequivalence; Draft 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 draft guidance for industry entitled ''Topical Dermatologic Corticosteroids: In Vivo Bioequivalence.'' This draft guidance is intended to assist applicants who submit abbreviated new drug applications (ANDAs) for topical dermatologic corticosteroid products of all potency groups (referred to in this notice as topical corticosteroids). The draft guidance describes recommendations for an in vivo pharmacodynamic approach to demonstrate the bioequivalence of topical corticosteroids. When finalized, this guidance will replace FDA's 1995 guidance for industry of the same name. Revising this guidance will provide clarity for potential ANDA applicants on the appropriate pilot and pivotal studies and other recommendations for pharmacodynamic approach to assess the bioequivalence of topical dermatologic corticosteroids. These recommendations have evolved since the original guidance was issued in 1995.

DATES: Submit either electronic or written comments on the draft guidance by December 23, 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–2170 for ''Topical Dermatologic Corticosteroids: In Vivo Bioequivalence.'' 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