identify an attribute of the approved drug products that the proposed compounded drug product is intended to address. FDA finds no basis to conclude that an attribute of the FDA-approved products makes them medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation and that a proposed compounded product is intended to address.

2. Whether the Drug Product Must Be Compounded from a Bulk Drug Substance

Because the nominations do not identify specific differences between drug products that would be compounded using rocuronium bromide and approved drug products containing rocuronium bromide, there is nothing for FDA to evaluate under question 2.

## VI. Conclusion

For the reasons stated above, we tentatively conclude that there is a clinical need for outsourcing facilities to compound drug products using the bulk drug substances arginine HCl for oral use only, lysine HCl for oral use only, and lysine HCl in combination with FDA-approved single-ingredient arginine HCl for injection for intravenous use only. We therefore propose to include those bulk drug substances on the 503B Bulks List as described in this notice.

At this time, we find no basis to conclude that there is a clinical need for outsourcing facilities to compound drug products using the bulk drug substances etomidate, furosemide, and rocuronium bromide. Therefore, we propose not to include these bulk drug substances on the 503B Bulks List.

## VII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*1. FDA, Guidance for Industry, ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act,'' January 2017 (available at *https://www.fda.gov/media/94402/download*).

*2. FDA, Guidance for Industry, ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act,'' March 2019 (available at *https://www.fda.gov/media/121315/download*).

*3. FDA Memorandum to File, ''Clinical Need for Arginine Hydrochloride in Compounding Under Section 503B of the FD&C Act,'' October 2022.

*4. FDA Memorandum to File, ''Clinical Need for Lysine Hydrochloride in Compounding Under Section 503B of the FD&C Act,'' October 2022.

5. Singh, B.B., J. Udani, S.P, Vinjamury, C, Der-Martirosian, et al, 2005, ''Safety and Effectiveness of an L-lysine, Zinc, and Herbal-Based Product on the Treatment of Facial and Circumoral Herpes,'' *Alternative Medicine Review,* 10: 123–7

*6. FDA Memorandum to File, ''Clinical Need for Lysine Hydrochloride (HCl) Alone and in Combination With Arginine HCl in Compounding Under Section 503B of the FD&C Act,'' October 2022.

*7. Letter from SNMMI to FDA dated May 25, 2018, requesting FDA place arginine and lysine on the 503B Bulks List.

Dated: November 17, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–25549 Filed 11–22–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–2796]**

### Bristol Myers Products Inc.; Proposal To Withdraw Approval of a New Drug Application for Bufferin (Aspirin) Tablets; 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 a new drug application (NDA) for Bufferin (aspirin) tablets, for which Bristol Myers Products Inc., 1350 Liberty Ave., Hillside, NJ 07205 is the last holder of record, and is announcing an opportunity for the holder of the NDA to request a hearing on this proposal. The basis for the proposal is that the holder of the NDA has repeatedly failed to file required annual reports for this NDA.

**DATES:** The holder of the NDA may submit a request for a hearing by December 23, 2022. Submit all data, information, and analyses upon which the request for a hearing relies by January 23, 2023. Submit electronic or written comments by January 23, 2023.

**ADDRESSES:** The request for a hearing may be submitted by the holder of the NDA 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–2796 for ''Bristol Myers Products Inc.; Proposal To Withdraw Approval of a New Drug Application for Bufferin (Aspirin) Tablets; 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. The holder of the NDA 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. Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 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–2796 for ''Bristol Myers Products Inc.; Proposal To Withdraw Approval of a New Drug Application for Bufferin (Aspirin) Tablets; 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 21 CFR 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:** 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.

**SUPPLEMENTARY INFORMATION:** On June 30, 1948, NDA 006499 for Bufferin (aspirin) tablets became effective. 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 is identifying Bristol Myers Products Inc. as the NDA holder of record in this **Federal Register** notice, but in the event that another entity holds NDA 006499, the Agency is also providing notice to that entity.

The holder of an approved NDA to market a new drug for human use is required to submit annual reports to FDA concerning its approved NDA under § 314.81 (21 CFR 314.81). The holder of NDA 006499 for Bufferin (aspirin) tablets has repeatedly failed to submit the required annual reports.

Therefore, notice is given to the holder of NDA 006499 and to all other interested persons that the Director of CDER proposes to issue an order, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of NDA 006499 and all amendments and supplements thereto on the grounds that the holder of the NDA has failed to submit reports required under § 314.81.

In accordance with section 505 of the FD&C Act and part 314 (21 CFR part 314), the holder of NDA 006499 is hereby provided an opportunity for a hearing to show why the approval of NDA 006499 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 NDA 006499.

Withdrawal of the approval of NDA 006499 will not impact nonprescription aspirin products that are legally marketed without an approved application as over the counter (OTC) monograph drugs in accordance with section 505G of the FD&C Act (21 U.S.C 355h), 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*). 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 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 FD&C Act and will be unaffected by withdrawal of approval of NDA 006499.

To seek a hearing, the NDA holder 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 the NDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by the NDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the application and constitutes a waiver of any contentions concerning the legal status of the drug product. FDA will then withdraw approval of the application, 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 application 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. 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.

Paper 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: November 17, 2022.

**Patrizia Cavazzoni,**

*Acting Director, Center for Drug Evaluation and Research.*

[FR Doc. 2022–25516 Filed 11–22–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–D–2922]**

### Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled ''Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' This guidance describes FDA's regulatory and enforcement priorities regarding preparation of beta-lactam oral antibiotic suspension products that appear on FDA's drug shortage list by a licensed pharmacist in a State-licensed pharmacy or Federal facility.

**DATES:** The announcement of the guidance is published in the **Federal Register** on November 23, 2022.

**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–2022–D–2922 for ''Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' 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