Estimated Total Annual Burden Hours: 3,410.

Authority: Section 471(e)(4)(E) of the Act (42 U.S.C. 671), as amended by Public Law 115–123.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–04939 Filed 3–8–22; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1977–N–0015 (Formerly 77N–0187); DESI 7663]

Drugs for Human Use; Drug Efficacy Study Implementation; Potassium Aminobenzoate Oral Preparations; Withdrawal of Hearing Request; Withdrawal of New Drug Application; Final Resolution of Drug Efficacy Study Implementation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that all outstanding hearing requests regarding POTABA (potassium aminobenzoate) Tablets, Capsules, Powder, and Envules under Docket No. FDA–1977–N–0015 (formerly 77N–0187) (this Drug Efficacy Study Implementation (DESI) 7663) have been withdrawn. Therefore, as proposed in the notice of opportunity for hearing (NOOH), FDA finds that the products subject to the application identified in this docket, or any identical, related, or similar (IRS) products, have not been shown to be effective for use under the conditions of use prescribed, recommended, or suggested in the labeling, and hereby withdraws approval of the application under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This notice is applicable April 8, 2022.

ADDRESSES: 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 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

The most relevant background documents regarding this matter are available in the docket. However, additional background documents are available upon request (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Astrid Lopez-Goldberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5185, Silver Spring, MD 20993–0002, 301–796–3485, email: *Astrid.LopezGoldberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 1962, Congress amended the FD&C Act to require that new drugs be proven effective for their labeled indications, as well as safe, in order to obtain FDA approval (Drug Amendments of 1962 (Pub. L. 87–781)). These amendments also required FDA to conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. FDA contracted with the National Academy of Sciences/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved only for safety between 1938 and 1962. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The Agency reviewed and reevaluated the reports and published its findings in **Federal Register** notices. FDA's administrative implementation of the NAS/NRC reports was called the DESI. DESI covered the approximately 3,400 products specifically reviewed by the NAS/NRC, as well as the even larger number of IRS products that entered the market without FDA approval. If FDA's final DESI determination classifies a drug product as lacking substantial evidence of effectiveness for one or more indications, that drug product and those IRS to it may no longer be marketed for such indications and are subject to enforcement action as unapproved new drugs.

II. Final Resolution of Hearing Request Regarding Potassium Aminobenzoate Oral Preparations Under Docket No. FDA–1977–N–0015 (Formerly 77N–0187); DESI 7663

In a **Federal Register** notice published on August 28, 1970 (35 FR 13755), FDA announced its evaluation of a report received from the NAS/NRC under DESI 7663 regarding POTABA (potassium aminobenzoate) Tablets, Capsules, Powder, and Envules, New Drug Application (NDA) 007663, held by Glenwood LLC (formerly known as Glenwood Laboratories, Inc.), 83 Summit St., Tenafly, NJ 07670 (herein after ''Glenwood''). The notice stated that the drug products were possibly effective in the treatment of scleroderma, dermatomyositis, morphea, linear scleroderma, pemphigus, and Peyronie's Disease and lacked substantial evidence of effectiveness for the treatment of rheumatoid arthritis, sarcoidosis, and pulmonary fibrosis. Glenwood, and any other person marketing such drug products without approval, was given 60 days to revise its labeling to delete those indications for which substantial evidence of effectiveness was lacking and 6 months to submit data to provide substantial evidence of effectiveness for the indications for which the drug was regarded as possibly effective. The notice stated that, at the end of the 6-month period, FDA would evaluate the data to determine whether substantial evidence of effectiveness had been provided, and, if it had not, FDA would initiate the withdrawal of approval of NDA 007663 under section 505(e) of the FD&C Act (21 U.S.C. 355(e)).

Glenwood did not submit data to provide substantial evidence of effectiveness for the indications for which the drug was regarded as possibly effective within the period provided by the 1970 **Federal Register** notice, and the Agency issued a NOOH on the proposed withdrawal of approval of NDA 007663 in the **Federal Register** of February 4, 1972 (37 FR 2688).

In response to a court order, FDA published a notice in the **Federal Register** on December 14, 1972 (37 FR 26623), which stated that POTABA, among other drugs, could remain on the market pending completion of further scientific studies.

In a **Federal Register** notice published on August 19, 1977 (42 FR 41922), the Agency revoked the exemption granted in the December 14, 1972, notice pursuant to which POTABA had remained on the market pending its continued study. In a separate NOOH for DESI 7663, also published in the **Federal Register** of August 19, 1977 (42 FR 41921), FDA noted that Glenwood did not submit data providing substantial evidence of effectiveness and that no other person had submitted data or protocols or expressed an intention to perform clinical studies on potassium aminobenzoate. This notice reclassified the possibly effective indications to lacking substantial evidence of effectiveness and proposed to issue an order under section 505(e) of the FD&C Act withdrawing approval of Glenwood's NDA and all amendments

and supplements thereto on the grounds that new information, evaluated together with the evidence available when the application was approved, showed there is a lack of substantial evidence that the drug is effective under the conditions of use prescribed, recommended, or suggested in the labeling. The Agency again invited Glenwood, and any other interested person(s) who would be adversely affected by the withdrawal of approval of NDA 007663, to submit: (1) On or before September 19, 1977, a written notice of appearance and request for hearing and (2) on or before October 17, 1977, the data, information, and analyses relied upon to justify a hearing.

On September 12, 1977, Glenwood filed a written notice of appearance and requested a hearing, and on October 17, 1977, Glenwood submitted data in support of its hearing request. Along with these submissions, Glenwood requested that the Agency delay action on the hearing request until the firm had conducted another placebo-controlled study. Subsequently, Glenwood initiated a clinical trial at the Downstate Medical Center of the State University of New York and supplemented its hearing request with additional data, including a progress report on the clinical trial of POTABA conducted at the Downstate Medical Center.

Following a meeting between Glenwood and FDA on November 18, 1985, Glenwood sponsored another controlled clinical trial, and the final study report was submitted on February 4, 1993.

By letter dated October 21, 2010, FDA asked Glenwood whether it wanted to pursue its pending hearing request regarding POTABA. By letter dated November 11, 2010, Glenwood affirmed its hearing request.

By letter dated June 8, 2020, FDA again asked Glenwood whether it wanted to pursue its pending hearing request regarding POTABA. By letter dated July 2, 2020, Cheplapharm Arzneimittel GmbH, successor-in-interest to Glenwood LLC, stated that it did not wish to pursue the hearing request for POTABA.

III. Conclusions and Order

There are no outstanding hearing requests regarding potassium aminobenzoate oral preparations under Docket No. FDA–1977–N–0015, DESI 7663. Therefore, as proposed in the NOOH, FDA withdraws approval of NDA 007663 under section 505(e) of the FD&C Act.

Shipment in interstate commerce of any drug product identified in this docket under DESI 7663, or any IRS product, that is not the subject of an approved NDA or abbreviated new drug application is unlawful as of the effective date of this notice (see **DATES**). Any person who wishes to determine whether this notice covers a specific product should write to Astrid Lopez-Goldberg at the Center for Drug Evaluation and Research (see **FOR FURTHER INFORMATION CONTACT**). Firms should be aware that, after the applicable date of this notice (see **DATES**), FDA intends to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice.

IV. Discontinued Products

Firms must notify the Agency of certain product discontinuations in writing under section 506C(a) of the FD&C Act (21 U.S.C. 356c). See *http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142398.htm.* Some firms may have previously discontinued manufacturing or distributing products covered by this notice without discontinuing the listing as required under section 510(j) of the FD&C Act (21 U.S.C. 360(j)). Other firms may discontinue manufacturing or distributing listed products in response to this notice. All firms are required to electronically update the listing of their products under 510(j) of the FD&C Act to reflect discontinuation of unapproved products covered by this notice (21 CFR 207.57(b)). Questions on electronic drug listing updates should be sent to *eDRLS@fda.hhs.gov.* In addition to the required update, firms can also notify the Agency of product discontinuation by sending a letter, signed by the firm's chief executive officer and fully identifying the discontinued product(s), including the product National Drug Code number(s), and stating that the manufacturing and/or distribution of the product(s) have been discontinued. The letter should be sent electronically to Astrid Lopez-Goldberg (see **FOR FURTHER INFORMATION CONTACT**). FDA plans to rely on its existing records, including its drug listing records, the results of any future inspections, or other available information, when it identifies violative products for enforcement action.

Dated: March 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04971 Filed 3–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0075]

Food and Drug Administration Quality Metrics Reporting Program; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to solicit comments on changes to FDA's previously proposed quality metrics reporting program (QM Reporting Program). This notice describes considerations for refining the QM Reporting Program based on lessons learned from two pilot programs with industry that were announced in the **Federal Register** in June 2018, a Site Visit Program and a Quality Metrics Feedback Program, as well as stakeholder feedback on FDA's 2016 revised draft guidance for industry entitled ''Submission of Quality Metrics Data.'' FDA is interested in responses to the questions listed in section III of this document, in addition to any general comments on the proposed direction for the program. This notice is not intended to communicate our regulatory expectations for reporting quality metrics data to FDA but is instead intended to seek input from industry to inform the future regulatory approach.

DATES: Submit either electronic or written comments by June 7, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 7, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 7, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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://*