

FOR FURTHER INFORMATION CONTACT:
William Cody, Secretary; Phone: (202)
523-5725; Email: secretary@fmc.gov.

SUPPLEMENTARY INFORMATION: On December 28, 2021, the Commission issued three policy statements to provide guidance to shippers and others on bringing private party complaints at the Commission and to address barriers identified by the trade community as disincentives to filing actions at the agency. The Commission voted in September 2021 to adopt the recommendation of the Fact Finding Officer of Fact Finding No. 29: International Ocean Transportation Supply Chain Engagement to issue policy statements on the anti-retaliation provision of the Shipping Act (46 U.S.C. 41104(a)(3)), the standard for recovering attorney fees in private party complaints, and the ability of shippers' associations and trade associations to file a complaint with the Commission alleging a violation of the Shipping Act.

Policy Statement on Representative Complaints: In the first policy statement, the Commission restates that shippers' associations and trade associations may file complaints alleging violations of 46 U.S.C. Chapter 411.

Policy Statement on Attorney Fees: The second policy statement explains the Commission's approach on attorney fees and reiterates that a party who brings an unsuccessful complaint is not automatically required to pay the other party's attorney fees.

Policy Statement on Retaliation: Finally, in the third statement on retaliation, the Commission emphasizes that it broadly defines both who can bring a retaliation complaint, as well as the types of shipper activity that are protected under the existing retaliation prohibitions. This policy statement also addresses the proof necessary for certain retaliation complaints.

The policy statements can be found at the following link: <https://www.fmc.gov/resources-services/filing-a-shipping-act-complaint/>.

resources-services/filing-a-shipping-act-complaint/.

By the Commission.

William Cody,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Prevention Services Data Collection (OMB #0970-0529)

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Children's Bureau is requesting a 3-year extension of the Prevention Services Data Collection (OMB #0970-0529, expiration 7/31/2022). There are no changes requested to the form.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. You can also obtain copies of the proposed collection of information by emailing.

SUPPLEMENTARY INFORMATION:

Description: Section 471(e)(4)(E) of the Social Security Act (the Act) (42 U.S.C. 671), as amended by Public Law 115-123, requires state and tribal child welfare agencies to collect and report to ACF information on children receiving prevention and family services and programs. Title IV-E Agencies must report the following on a bi-annual basis:

- The specific services or programs provided
- The total expenditures for each of the services or programs provided
- The duration of the services or programs provided, and
- If the child was identified in a prevention plan as a candidate for foster care:
 - The child's placement status at the beginning, and at the end, of the 12-month period that begins on the date the child was identified as a candidate for foster care in a prevention plan; and
 - Whether the child entered foster care during the initial 12-month period and during the subsequent 12-month period.

To date, approximately $\frac{3}{4}$ of the Title IV-E Agencies have chosen to provide these prevention services; however, it is believed that this number will continue to increase over time as states voluntarily opt-in to the program in order to utilize IV-E funding to provide prevention programs and services to children and families.

The data collected will continue to inform federal policy decisions, program management, and responses to Congressional and Departmental inquiries. Specifically, the data will provide information about the use and availability of prevention services to children to prevent the need for foster care placement. The data contains personally identifiable information (date of birth and race/ethnicity).

Respondents: Title IV-E Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Prevention Services Data Collection	55	2	31	3,410

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]

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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:

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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., Tenaflly, 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