

validation reviews or complaint surveys, the state survey agency monitors corrections as specified at § 488.9.

++ CIHQ’s capacity to report deficiencies to the surveyed facilities and respond to the facility’s plan of correction in a timely manner.

++ CIHQ’s capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization’s survey process.

++ The adequacy of the CIHQ’s staff and other resources, and its financial viability.

++ CIHQ’s capacity to adequately fund required surveys.

++ CIHQ’s policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ CIHQ’s policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ CIHQ’s agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

**IV. Collection of Information Requirements**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**V. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of

this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: December 2, 2022.

**Lynette Wilson,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

[FR Doc. 2022–26596 Filed 12–6–22; 8:45 am]

**BILLING CODE 4120–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

[OMB No. 0970–0248]

**Submission for Office of Management and Budget (OMB) Review; Annual Report on State Maintenance-of-Effort (MOE) Programs—ACF–204 (Annual MOE Report) (Office of Management and Budget**

**AGENCY:** Office of Family Assistance, Administration for Children and Families, U.S. Department of Health and Human Services.

**ACTION:** Request for public comments.

**SUMMARY:** The Administration for Children and Families (ACF) is requesting a 3-year extension of the ACF–204 (Annual MOE Report; OMB #0970–0248, expiration November 30, 2022). There are no changes requested to this information collection.

**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](http://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 [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all emailed requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* The Annual MOE Report is used to collect descriptive program characteristics information on the programs operated by states and territories in association with their Temporary Assistance for Needy Families (TANF) programs. All state and territory expenditures claimed toward states and territories MOE requirements must be appropriate, *i.e.*, meet all applicable MOE requirements. The Annual MOE Report provides the ability to learn about and to monitor the nature of state and territory expenditures used to meet states and territories MOE requirements, and it is an important source of information about the different ways that states and territories are using their resources to help families attain and maintain self-sufficiency. In addition, the report is used to obtain state and territory program characteristics for ACF’s annual report to Congress, and the report serves as a useful resource to use in Congressional hearings about how TANF programs are evolving, in assessing state and the territory MOE expenditures, and in assessing the need for legislative changes.

*Respondents:* The 50 States of the United States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

**ANNUAL BURDEN ESTIMATES**

Instrument	Total number of respondents per year	Total number of annual responses per respondent	Average burden hours per response	Annual burden hours
ACF–204; Annual MOE Report .....	54	1	118	6,372

*Estimated Total Annual Burden Hours: 6,372.*

*Authority:* Section 402 of the Social Security Act (42 U.S.C. 602), as amended by Public Law 104–193, the

Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–26542 Filed 12–6–22; 8:45 am]

BILLING CODE 4184–82–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–N–1262]

#### Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that IMJUDO (tremelimumab), approved October 23, 2022, meets the criteria for redeeming a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:**

Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: [Cathryn.Lee@fda.hhs.gov](mailto:Cathryn.Lee@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that IMJUDO (tremelimumab), approved October 23, 2022, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>.

For further information about IMJUDO (tremelimumab), approved October 23, 2022, go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: December 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–26565 Filed 12–6–22; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2022–D–2301]

#### Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations; 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 “Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations.” This draft guidance is intended to clarify the key factors in determining the appropriate aluminum content in a small volume parenteral (SVP) drug product and/or a pharmacy bulk package (PBP) intended as a component of parenteral nutrition (PN) and provide FDA’s recommendations regarding the concentration of aluminum in SVP drug products and PBPs for PN. Additionally, this guidance is intended to assist applicants in determining the appropriate content and placement of information on aluminum in SVP and PBP human prescription drug product labeling.

**DATES:** Submit either electronic or written comments on the draft guidance by February 6, 2023 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–2301 for “Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations.” 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