

Statutory Authority: *Ms. L. v. U.S. Immigration and Customs Enforcement* (2023) Settlement Agreement (Section IV.B.), available at: <https://www.justice.gov/opa/file/1319516/dl?inline>.

Elizabeth Leo,

Policy Branch Chief, Office of Grants Policy, Office of Administration.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for Office of Management and Budget (OMB) Review; Revisions to Two Information Collections: Medical Assessment Form and Dental Assessment Form (OMB #0970-0466) and Mental Health Assessment Form and Public Health Investigation Forms, Tuberculosis and Non-Tuberculosis Illness (OMB #0970-0509)

**AGENCY:** Office of Refugee Resettlement, 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 proposing a change of the described potential uses of data for two information collections: Medical Assessment Form and Dental Assessment Form (OMB #: 0970-0466) and Mental Health Assessment Form and Public Health Investigation Forms, Tuberculosis and Non-Tuberculosis Illness (OMB: #0970-0509).

**DATES:** *Comments due* August 1, 2024. OMB has agreed to make a decision about the updates to these collections of information following a public comment period of 30 days. Therefore, a comment is best assured of having its full effect if ACF receives it within 30 days of publication.

**ADDRESSES:** You can obtain copies of the proposed changes and submit comments by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all requests by the title of the information collection.

#### SUPPLEMENTARY INFORMATION:

*Description:* The following two ORR information collections capture health data on children in ORR care:

- Medical Assessment Form and Dental Assessment Form
- Mental Health Assessment Form and Public Health Investigation Form:

Active TB, and Public Health Investigation Form: Non-TB Illness

The current description of purpose and use of the data collected states that confidential and sensitive health information will only be shared with external stakeholders (including other Federal agencies) for public health purposes (e.g., contact investigations to identify children exposed to a reportable infectious disease). However, ORR has identified a need to share the health data of specific unaccompanied children with the Department of Homeland Security (DHS) which falls outside of the stated limitations. The need to communicate with DHS occurs when a newly referred child arrives at an ORR facility ill or requires emergent/urgent healthcare services shortly after placement and ORR was not notified in advance. For DHS to investigate the event, ORR must share confidential and sensitive health information including the child's alien number, name, signs/symptoms, diagnoses, and date of diagnosis. The goal of this data sharing effort is to identify areas of potential improvement in delivery of healthcare services and continuity of care for children transferred from DHS to Health and Human Services custody.

*Respondents:* Healthcare providers (pediatricians, medical specialists, and dentists), mental health professionals (psychiatrists, psychiatric nurse practitioners or physician's assistants, licensed psychologist or any other community based licensed mental health provider (e.g., social worker), care provider program staff.

*Annual Burden Estimates:* No changes. For current burden estimates, see information below:

- [https://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=202312-0970-002](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202312-0970-002)
- [https://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=202312-0970-003](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202312-0970-003)

*Authority:* 6 U.S.C. 279; Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al., v. Janet Reno, Attorney General of the United States, et al.*, Case No. CV 85-4544-RJK [C.D. Cal. 1996]).

Mary C. Jones,

ACF/OPRE Certifying Officer.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2023-E-3130 and FDA-2023-E-3135]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; XENPOZYME

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for XENPOZYME and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 3, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 30, 2024. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 3, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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://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