

tribal governments operating Head Start and Early Head Start programs.

The agenda for the scheduled OHS Tribal Consultations reflects the statutory purposes of Head Start tribal consultations related to meeting the needs of AI/AN children and families. OHS will also highlight the progress made in addressing issues and concerns raised in the previous OHS Tribal Consultations.

The consultation sessions include elected or appointed leaders of tribal governments and their designated representatives. Designees must have a letter from the tribal government authorizing them to represent the tribe. Tribal governments must submit the designee letter at least 3 days before the consultation sessions to Todd Lertjuntharangool at [Todd.Lertjuntharangool@acf.hhs.gov](mailto:Todd.Lertjuntharangool@acf.hhs.gov). Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

Within 45 days of the consultation sessions, a detailed report of each consultation session will be available for all tribal governments receiving funds for Head Start and Early Head Start programs. Tribes can submit written testimony for the report to Todd Lertjuntharangool at [Todd.Lertjuntharangool@acf.hhs.gov](mailto:Todd.Lertjuntharangool@acf.hhs.gov) prior to each consultation session or within 30 days of each meeting. OHS will summarize oral testimony and comments from the consultation sessions in each report without attribution, along with topics of concern and recommendations.

Roshelle M. Brooks,  
ACF Certifying Officer.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Notice of Federal Review of the American Samoa Protection and Advocacy System (P&A)

**AGENCY:** Administration for Community Living, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** Representatives of the Administration on Disabilities (AoD), Administration for Community Living (ACL), will be conducting a federal review of the American Samoa Protection and Advocacy System (P&A) on September 19–23, 2022. AoD is

soliciting comments from interested parties on your experiences with the program, and strategies employed by P&A in meeting the needs of individuals with developmental disabilities and their families in American Samoa. You are encouraged to share your experiences by way of any of the following methods:

**DATES:** Comments should be received by September 1, 2022 in order to be included in the final report.

**ADDRESSES:** EMAIL: [Elizabeth.Leef@acl.hhs.gov](mailto:Elizabeth.Leef@acl.hhs.gov), TELEPHONE: 202-475-2482, MAIL COMMENTS TO: Elizabeth Leef, Program Specialist, Administration on Disabilities, Administration for Community Living, 330 C Street SW, 1st Floor, Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:**

Elizabeth Leef, Administration for Community Living, Administration on Disabilities, 330 C Street SW, 1st Floor, Washington, DC 20201, 202-475-2482.

Authority: 45 CFR 1326.21(h)

Dated: June 15, 2022.

Alison Barkoff,

Acting Administrator & Assistant Secretary for Aging.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-3815]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishment Registration and Device Listing for Manufacturers and Importers of Devices

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 25, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs,

OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0625. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Establishment Registration and Device Listing for Manufacturers and Importers of Devices—21 CFR Part 807, Subparts A Through D

OMB Control Number 0910-0625—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) and implementing regulations in 21 CFR part 807, subparts A through D (part 807, subparts A through D), medical device establishment owners and operators are required to electronically submit establishment registration and device listing information. Complete and accurate registration and listing information is necessary to accomplish a number of statutory and regulatory objectives, such as: (1) identification of establishments producing marketed medical devices; (2) identification of establishments producing a specific device when that device is in short supply or is needed for national emergency; (3) facilitation of recalls for devices marketed by owners and operators of device establishments; (4) identification and cataloging of marketed devices; (5) administering postmarketing surveillance programs for devices; (6) identification of devices marketed in violation of the law; (7) identification and control of devices imported into the country from foreign establishments; and (8) scheduling and planning inspections of registered establishments under section 704 of the FD&C Act (21 U.S.C. 374).

Respondents to this information collection are owners or operators of establishments that engage in the manufacturing, preparation, propagation, compounding, or processing of a device or devices, who must register their establishments and