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.* 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* 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.*

[FR Doc. 2022–13532 Filed 6–23–22; 8:45 am]

**BILLING CODE 4184–40–P**

## 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,* 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.*

[FR Doc. 2022–13462 Filed 6–23–22; 8:45 am]

**BILLING CODE 4154–01–P**

## 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 *oira_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.*

**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

submit listing information for each of their devices in commercial distribution. Notwithstanding certain exceptions, foreign device establishments that manufacture, prepare, propagate, compound, or process a device that is imported or offered for import into the United States must also comply with the registration and listing requirements. The number of respondents is based on data from the FDA Unified Registration and Listing System (FURLS). Burden estimates are based on recent experience with the medical device registration and listing program, electronic system operating experience, and previous data estimates.

In the **Federal Register** of February 8, 2022 (87 FR 7187), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section; activity | Number of respondents | Annual frequency per response | Total annual responses | Hours per response | Total hours [2] |
|---|---|---|---|---|---|
| 807.20(a)(5); [3] Initial submittal of manufacturer information by initial importers. | 4,125 | 1 | 4,125 | 1.75 | 7,219 |
| 807.20(a)(5); [4] Annual submittal of manufacturer information by initial importers. | 4,125 | 1 | 4,125 | 0.1 (6 minutes) | 413 |
| 807.21(a); [3] Creation of electronic system account | 5,355 | 1 | 5,355 | 0.5 (30 minutes) | 2,678 |
| 807.21(b); [4] Annual request for waiver from electronic registration & listing. | 1 | 1 | 1 | 1 | 1 |
| 807.21(b); [3] Initial request for waiver from electronic registration & listing. | 1 | 1 | 1 | 1 | 1 |
| 807.22(a); [3] Initial registration & listing | 5,355 | 1 | 5,355 | 1 | 5,355 |
| 807.22(b)(1); [4] Annual registration | 28,496 | 1 | 28,496 | 0.5 (30 minutes) | 14,248 |
| 807.22(b)(2); [4] Other updates of registration | 2,671 | 1 | 2,671 | 0.5 (30 minutes) | 1,336 |
| 807.22(b)(3); [4] Annual update of listing information | 26,871 | 1 | 26,871 | 0.5 (30 minutes) | 13,436 |
| 807.22(b)(4) Changes to listing information (outside of annual listing requirement period): | | | | | |
| Voluntary reporting of transfer of 510(k) clearance (outside of annual listing requirement period). | 4,080 | 1 | 4,080 | 0.25 (15 minutes) | 1,020 |
| Submission of 510(k) transfer documentation when more than one party lists the same 510(k). | 2,033 | 1 | 2,033 | 4 | 8,132 |
| 807.26(e); [4] Labeling & advertisement submitted at FDA request. | 9 | 1 | 9 | 1 | 9 |
| 807.34(a); [3] Initial registration & listing when electronic filing waiver granted. | 1 | 1 | 1 | 1 | 1 |
| 807.34(a); [4] Annual registration & listing when electronic filing waiver granted. | 1 | 1 | 1 | 1 | 1 |
| 807.40(b)(3); [4] Annual update of U.S. agent information | 6,101 | 1 | 6,101 | 0.5 (30 minutes) | 3,051 |
| 807.40(b)(2); [4] U.S. agent responses to FDA requests for information. | 1,535 | 1 | 1,535 | 0.25 (15 minutes) | 384 |
| 807.41(a); [4] Identification by foreign establishments of importers, defined in 807.3, of the establishment's devices. | 14,017 | 1 | 14,017 | 0.5 (30 minutes) | 7,009 |
| 807.41(b); [4] Identification of other importers (defined in 807.3(x)–(y)) that facilitate import by foreign establishments. | 14,017 | 1 | 14,017 | 0.5 (30 minutes) | 7,009 |
| Total | | | | | 71,303 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals are rounded to the nearest whole number.
[3] One-Time Burden—Firm only provides initially.
[4] Recurring Burden—Firm is required to review annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR section | Number of respondents | Annual frequency per recordkeeper | Total annual records | Hours per record | Total hours |
|---|---|---|---|---|---|
| 807.25(d); [2] Labeling and advertisements available for review. | 17,032 | 4 | 68,128 | 0.5 (30 minutes) | 34,064 |
| 807.26; [2] List of officers, directors, and partners | 33,851 | 1 | 33,851 | .25 (15 minutes) | 8,463 |
| Total | | | | | 42,527 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Recurring burden—Firm is required to keep records.

Our estimates for creating new user accounts under § 807.21(a) are based on the recent number of owners or operators. An owner or operator only creates an account one time when they register for the first time (initial

registration). Once the account is created, the owner or operator uses the account as long as the establishment is registered. If an owner or operator changes, the new owner or operator creates a new owner or operator account and transfers the ownership of the establishment to their owner or operator account. Once they create an owner or operator account, they use the account for as long as the company is registered. Under § 807.22(b)(4), changes to listing information may be made at times outside of the annual listing requirement period, such as when a change is made to a previously listed device.

The draft guidance entitled ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers'' (December 2014), which contained instructions for the proposed voluntary information collection, has recently been withdrawn. While notification of transfer of ownership information is not currently required, our medical device registration and listing website [1] communicates procedures for notifying FDA of the transfer of a premarket notification (510(k)) clearance from one person to another. The notification is used to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up to date. Although submission of information regarding the transfer of a 510(k) clearance is not required under the regulations, we regularly receive such notifications from respondents.

We estimate that annually 78 percent of 510(k)s may be initially listed or updated outside of the annual registration requirement (about 4,080 510(k)s per year). We assume it will take 15 minutes for each listing, for a total reporting burden of 1,020 hours.

We estimate 2,033 instances of more than one party claiming to be a 510(k) holder for a specific device as part of annual registration and listing. We determined our estimate by identifying the average number of unique 510(k) device listings entered in FURLS between fiscal years 2017 and 2019 that conflict with a listing already entered by another party (5,304), dividing that number by the number of years (3) and multiplying by the average number of parties claiming to be the 510(k) holder when there is a conflict in the current FURLS database (2.3), then dividing the result by 2 (because only one company per listing will submit the appropriate documentation to show that they are the current 510(k) holder).

The registration and listing website identifies potential documentation a party could submit to FDA to establish the transfer of a 510(k) clearance to a new owner or operator. Based on the amount of time to locate the information, copy it, and submit a copy, we assume it takes respondents an average of 4 hours to establish the transfer of a 510(k) clearance.

The estimate for § 807.25(d) in table 2 of this document (recordkeeping burden) reflects the requirement that owners or operators maintain a historical file containing the labeling and advertisements in use. The estimate for § 807.26 reflects the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only when requested by FDA. However, it is assumed that some effort will need to be expended to keep such records current.

The recurring burden for the data collection under § 807.41 (import-related information provided by foreign companies exporting to the United States) was estimated based on data from previous years. Foreign companies identify readily available contact information at the time of registration. After completing their initial registration, they are required to review the importer information annually. When they review the importer information annually, they simply verify the importer information is accurate. If it is and no changes are needed, the foreign establishment's official correspondent checks the certification and submits the annual registration. If they need to make changes to the importer information, they can do so at any time and use a spreadsheet to update more than one importer at a time to their registration. The use of the spreadsheet reduces the burden to the official correspondent of the foreign establishment.

Our estimated burden for the information collection reflects an overall increase of 10,880 hours and a corresponding increase of 28,430 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last 3 years.

Dated: June 14, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–13522 Filed 6–23–22; 8:45 am]

**BILLING CODE 4164–01–P**

[1] *https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing.*

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–D–4368]**

## Assessing the Effects of Food on Drugs in Investigational New Drugs and New Drug Applications—Clinical Pharmacology Considerations; 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 final guidance for industry entitled ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' This guidance provides recommendations to sponsors planning to conduct food-effect (FE) studies for orally administered drug products as part of investigational new drug applications (INDs), new drug applications (NDAs), and supplements to these applications. This guidance finalizes the draft guidance of the same title issued on February 26, 2019.

**DATES:** The announcement of the guidance is published in the **Federal Register** on June 24, 2022.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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