between the publication of the notice and the associated files being publicly available. For this reason, we are publishing the 30-day notice again. *Form Number:* CMS–2540–24 (OMB control number: 0938–0463); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 14,189; *Total Annual Responses:* 14,189; *Total Annual Hours:* 2,866,178. (For policy questions regarding this collection contact Luann Piccione at 410–786–5423.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–11741 Filed 5–28–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meetings

AGENCY: Office of Early Childhood Development (ECD), Office of Head Start (OHS), and Office of Child Care (OCC), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Head Start Act, notice is hereby given of one joint Tribal consultation session to be held between HHS/ACF ECD, OHS, and OCC leadership and the leadership of Tribal governments operating Tribal Maternal, Infant, and Early Childhood Home Visiting; Tribal Child Care and Development Fund; and Head Start and Early Head Start programs. The purpose of this consultation session is to discuss ways to better meet the needs of Tribal children and their families and issues affecting the delivery of early childhood services in their geographic locations. The consultation will also provide an opportunity for discussion on the review and promulgation of Head Start Program Performance Standards, as required under the Head Start Act. To meet this legislative requirement, one Tribal consultation will be held as part of HHS/ACF or ACF Tribal consultation sessions.

DATES: The meetings will take place July 9 and 10, 2024, at the following times:

- July 9 from 9 a.m.–5 p.m. Mountain Standard Time; and
- July 10 from 9 a.m.–3 p.m. Mountain Standard Time

ADDRESSES: The meetings are in-person in Fort McDowell, Arizona, at:

We-Ko-Pa Casino Resort, 10438 WeKoPa Way, Fort McDowell, AZ 85264

FOR FURTHER INFORMATION CONTACT: Todd Lertjuntharangool, Regional Program Manager, Region 11, Office of Head Start, email *Todd.Lertjuntharangool@acf.hhs.gov,* or phone (866) 763–6481. Additional information and online meeting registration will be forthcoming.

SUPPLEMENTARY INFORMATION: In accordance with section 640(l)(4) of the Head Start Act, 42 U.S.C. 9835(1)(4), ACF announces a joint Tribal consultation session to be held between HHS/ACF ECD, OHS, and OCC leadership and the leadership of Tribal governments operating Tribal Maternal, Infant, and Early Childhood Home Visiting; Tribal Child Care and Development Fund; and Head Start and Early Head Start programs.

The agenda for the scheduled joint consultation reflects the statutory purposes of Head Start Tribal consultations related to meeting the needs of American Indian and Alaska Native (AIAN) children and families and will include the opportunity to discuss topics such as the Tribal Request for Information and recent changes to AIAN Head Start eligibility requirements. The consultation will also provide an opportunity for discussion on the review and promulgation of Head Start Program Performance Standards under section 641A(a)(2)(D) of the Head Start Act. OHS will also highlight the progress made in addressing issues and concerns raised in the previous OHS Tribal consultations.

The consultation session includes 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 session to *AIANheadstart@acf.hhs.gov*. Other representatives of Tribal organizations and Native non-profit organizations are welcome to attend as observers.

Within 45 days of the consultation session, 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 *AIANheadstart@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.

Khari M. Garvin,

Director, Office of Head Start.

Megan E. Steel,

ACF Certifying Officer.

[FR Doc. 2024–11783 Filed 5–24–24; 11:15 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2149]

Agency Information Collection Activities; Proposed Collection; Comment Request; De Novo Classification Process (Evaluation of Automatic Class III Designation)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions related to the De Novo Classification Process.

DATES: Either electronic or written comments on the collection of information must be submitted by July 29, 2024.

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 July 29, 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 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–2024–N–2149 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; De Novo Classification Process (Evaluation of Automatic Class III Designation).'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: 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.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

De Novo Classification Process (Evaluation of Automatic Class III Designation)—21 CFR Part 860, Subpart D

OMB Control Number 0910–0844—Extension

This information collection supports FDA regulations and information collection discussed in associated guidance. Sections 201(h), 513(a) and (f), 701(a), and 704 of the Federal Food, Drug, and Cosmetic (FD&C Act) (21 U.S.C. 321(h), 360c(a) and (f), 371(a), and 374) establish a comprehensive system for the regulation of medical devices intended for human use. Section 513(f)(2) of the FD&C Act provides for a ''De Novo'' classification process, most recently amended by section 3101 of the 21st Century Cures Act (Pub. L. 114–255). The final rule ''Medical Device De Novo Classification Process'' (86 FR 54826), established 21 CFR part 860, subpart D (sections 860.200 through 860.260) to implement provisions in section 513(f)(2) of the FD&C Act. These regulations govern format and content elements for De Novo device classification requests, as well as withdrawal of the requests, and explain FDA procedures for acceptance, review, and granting or denying a request.

In addition to regulatory requirements set forth in 21 CFR part 860, subpart D, the guidance document entitled ''Acceptance Review for De Novo Classification Requests'' communicates our thinking on criteria set out in 21 CFR part 860.230, in assessing whether a De Novo request should be accepted for substantive review. The guidance document includes an ''Acceptance Checklist'' to assist respondents in this regard.

The collections of information described by this notice are necessary to satisfy the previously mentioned statutory requirements for administration of this voluntary

submission program. FDA uses the information to evaluate whether a medical device may be reclassified from Class III into Class I or II, and if applicable, to determine the general and/or special controls necessary to sufficiently regulate the medical device. Respondents to this information collection are private sector or other for-profit businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR part 860, subpart D; information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 860.210, 860.220, 860.230; De Novo requests—format, content, and acceptance elements.	79	1	79	182 hours	14,378
§ 860.230; FDA acceptance of request (*GFI Acceptance Checklist;* Appendix A) [1].	79	1	79		
§ 860.250; withdrawal of request	5	1	5	0.17 (10 mins.)	1
Total			84		14,379

[1] FDA assumes activities associated with review of the Acceptance Checklist are included in burden for submission of requests captured in row 1.

Our estimated burden for the information collection reflects an overall increase of 2,002 hours and a corresponding increase of 11 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: May 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11743 Filed 5–28–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4805]

Maria Anzures-Camarena: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Maria Anzures-Camarena from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Anzures-Camarena was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Ms. Anzures-Camarena was given notice of the proposed debarment and an opportunity to request a hearing to show why she should not be debarred. As of March 6, 2024, (30 days after receipt of the notice), Ms. Anzures-Camarena has not responded. Ms. Anzures-Camarena's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable May 29, 2024.

ADDRESSES: Any application by Ms. Anzures-Camarena for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–4805. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access