Estimated Total Annual Burden Hours: 3,339.

Authority: Section 640(a)(2)(D) and section 649 of the Improving Head Start for School Readiness Act of 2007.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–24951 Filed 11–15–21; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Evidence Based Program Fidelity Surveys [OMB #0985–New]

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the information collection requirements for the Evidence Based Program Fidelity Surveys [OMB #0985–New].

DATES: Submit written comments on the collection of information by December 16, 2021.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice online at *www.reginfo.gov/public/do/PRAMain.* Find the information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments can also be submitted By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Susan Jenkins, Administration for Community Living, Washington, DC 20201, 202–795–7369 or by email: *Susan.Jenkins@acl.hhs.gov.*

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

The Administration for Community Living (ACL) is requesting approval to collect data for the Evidence Based Program Fidelity Surveys [OMB #0985–New]. The Evidence Based Program Fidelity Surveys will be used by ACL to evaluate the fidelity with which ACL's grantee organizations, under the Older Americans Act, implement the required evidence-based programs. States that receive Older Americans Act funds under Title III–D are required to spend those funds on evidence-based programs to improve the health and well-being of their clients and to reduce disease and injury. Since 2003, the aging services network has been steadily moving towards wider implementation of disease prevention and health promotion programs that are based on scientific evidence and demonstrated to improve the health of older adults. The FY 2012 Congressional appropriations law included, for the first time, an evidence-based requirement related to Title III–D funds.

The results of this information collection will be used by ACL/AoA to:

- Effectively report its results to the President, to Congress, to the Department of Health and Human Services and to the public.
- Assess the effectiveness of ACL and its grantees in monitoring program fidelity.
- Aid in program refinement and continuous improvement.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** on, July 12, 2021 in 86 FR 13720. There were 0 public comments received during the 60-day FRN.

Estimated Program Burden:

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Grantee: Program selection process and survey	103	1	2.00	206
Local Implementation Organization Survey	412	1	0.58	239
Total:	515	1	0.86	445

Dated: November 9, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2021–24923 Filed 11–15–21; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1992–N–0011]

Sanyasi Raju Kalidindi; Grant of Special Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has issued an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) granting special termination of the debarment of Sanyasi Raju Kalidindi. FDA based the order on a finding that Dr. Kalidindi provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction and that terminating Dr. Kalidindi's debarment served the interest of justice and protected the integrity of the drug approval process.

DATES: The order became effective September 15, 2021.

ADDRESSES: Comments should reference Docket No. FDA–1992–N–0011 and be sent to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Karena Cooper, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, MD 20993, 301 796–1612.

SUPPLEMENTARY INFORMATION: In a **Federal Register** notice dated April 21, 1993 (58 FR 21470), FDA debarred Dr. Kalidindi from providing services in any capacity to a person with an approved or pending drug product

application under section 306(a) of the FD&C Act (21 U.S.C. 335a(a)). FDA based the debarment on a finding under section 306(a)(2) of the FD&C Act that Dr. Kalidindi had been convicted of a felony under Federal law for conduct relating to the development, or approval, of any drug product or otherwise relating to the regulation of a drug product.

Section 306(d)(4) of the FD&C Act provides that any individual debarred under section 306(a)(2) may apply to FDA for special termination of debarment. Pursuant to section 306(d)(4)(C)–(D), FDA may grant a request for special termination and limit the period of debarment to less than permanent but no less than 1 year if the Agency finds: (1) That the individual has provided substantial assistance in the investigations or prosecutions of offenses described in section 306(a) or (b) of the FD&C Act, or relating to any matter under the jurisdiction of FDA and (2) that doing so best serves the interest of justice and protects the integrity of the drug approval process.

On May 27, 1998, FDA denied a previous petition for special termination of debarment submitted by Dr. Kalidindi. On January 13, 2020, Dr. Kalidindi again petitioned for special termination of debarment under section 306(d)(4) of the FD&C Act. On April 10, 2020, FDA's Office of Regulatory Affairs proposed denying that petition and offered Dr. Kalidindi an opportunity to request a hearing on the proposal to deny the petition. On May 9, 2020, Dr. Kalidindi requested a hearing and, on June 8, 2020, submitted materials in support of his hearing request.

By a decision dated September 15, 2021, FDA's Chief Scientist granted Dr. Kalidindi's petition for special termination based on her conclusion that doing so best served the interest of justice and protected the integrity of the drug approval process. In so concluding, she found that there were no genuine and substantial issues of fact with respect to the level and scope of substantial assistance provided by Dr. Kalidindi in the investigation and prosecution of others for offenses described in section 306(a) or (b) of the FD&C Act, or otherwise relating to FDA's jurisdiction, and that the level and scope of such substantial assistance, among other considerations, justified special termination of his debarment after 28 years. The Chief Scientist's decision is available at *https://www.fda.gov/media/152270/download.* The decision is also available at *https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-debarment-list-drug-product-applications/fda-expired-debarment-list-drug-product-applications.*

Dated: November 4, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24973 Filed 11–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–2167 and FDA–2020–E–2168]

Determination of Regulatory Review Period for Purposes of Patent Extension; QINLOCK

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 QINLOCK and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 18, 2022. 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 May 16, 2022. 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. Electronic comments must be submitted on or before January 18, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 Nos. FDA–2020–E–2167 and FDA–2020–E–2168 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; QINLOCK.'' 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