circular. If an alternative standard is proposed, the offeror must furnish data and/or information regarding the alternative in sufficient detail for the Government to determine if it meets the Government's requirements.

We believe the burden for FAR 52.211–7 to be negative, as it is purely a permissive means for offerors to propose reducing regulatory burden on a given solicitation. There are other places A–119 has an effect, though we believe these to be positive. One is by enabling the single process initiative. Another is the general replacement of Mil standards with commercial standards, *e.g.,* ISO 9000. Also, A–119 is the basis for the language in FAR 53.105, which reduces the chaos in data standards development. The whole purpose of A–119 was to reduce regulatory burden by promoting the use of industry standards in lieu of federal ones.

To the extent that the data on the annual frequency of the use of voluntary consensus standards under FAR 52.211–7 is not available, we believe 100 is reasonable. As an aside, FAR part 45 recognizes the use of voluntary consensus standards in the management of Government property. However, in these cases, there is no Government standard per se, with the voluntary consensus standard serving as the Government standard. Consequently, when under part 45 voluntary consensus standards are used, they are not an alternative to a Government standard under FAR 52.211–7.

This collection implements OMB Circular A–119, Federal Participation in the Development and Use of Voluntary Consensus Standards. FAR solicitation provision 52.211–7, Alternatives to Government-Unique Standards, is the collection instrument. We have previously indicated that ''to the extent that the data on the annual frequency of the use of voluntary consensus standards under FAR 52.211–7 is not available, we believe that 100 is reasonable.'' This is the number that has been reported since the inception of this PRA collection, which indicates that revised data has been consistently unavailable since responses are provided to contracting personnel at the local level in response to a local solicitation. We checked the FPDS data dictionary and there are no codes to flag data fields or provide a count of when Mil standards are used in solicitations/contracts. Considering the lack of FPDS or other data, we recommend continuing the PRA coverage at the current level.

B. Public Comment

A 60 day notice was published in the **Federal Register** at 82 FR 51256, on November 3, 2017. One comment was received; however, it was not substantive, and did not change the estimate of the burden.

C. Annual Reporting Burden

Respondents: 100.
Responses per Respondent: 1.
Total Responses: 100.
Hours per Response: 1.
Total Burden Hours: 100.
Affected Public: Businesses or other for-profit and not-for-profit.
Respondent's Obligation: Required to obtain or retain benefits.
Reporting Frequency: On occasion.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0153, OMB Circular A–119, in all correspondence.

Dated: January 12, 2018.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2018–00779 Filed 1–17–18; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0890]

William Ralph Kincaid; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is denying William Ralph Kincaid's (Kincaid's) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Kincaid 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 Kincaid was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Kincaid was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Kincaid submitted a request for hearing but failed to file with the Agency information and analysis sufficient to create a basis for a hearing.

DATES: This order is applicable January 18, 2018.

ADDRESSES: Any application by Kincaid for special termination of debarment under section 306(d) of the FD&C Act (application) may be submitted 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

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 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: Your application must include the Docket No. FDA–2015–N–0890. An application will be placed in the docket and, unless 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.

• *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. 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 application 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, 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 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, MD 20993, 301–796–8618.

SUPPLEMENTARY INFORMATION:

I. Background

On June 24, 2013, the U. S. District Court for the Eastern District of Tennessee entered a criminal judgment against William Ralph Kincaid pursuant to his guilty plea. Kincaid pled guilty to a felony under the FD&C Act, namely receiving in interstate commerce a misbranded drug with intent to defraud or mislead, in violation of sections 301(c) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(c) and 333(a)(2)) and 18 U.S.C. 2. The basis for this conviction was Kincaid's admission that he obtained drugs from Quality Specialty Products (QSP), a foreign company, for use at East Tennessee Hematology-Oncology Associates, P.C. (McLeod Cancer). These drugs were not FDA approved and were misbranded in that they lacked adequate directions for use and were manufactured in an establishment that was not registered with FDA and that did not list with FDA the drug products it manufactured. From approximately September 2007 to early 2008 and from August 2009 to February 2012, McLeod Cancer purchased more than $2 million in misbranded unapproved drugs for use at McLeod Cancer. Additionally, Kincaid and McLeod Cancer billed Medicare, TennCare, and other government health benefit programs approximately $2.5 million for these unapproved drugs.

Kincaid is subject to debarment based on a finding, under section 306(a)(2) of the FD&C Act (21 U.S.C. 335a(a)(2)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. By the letter dated May 20, 2015, FDA notified Kincaid of a proposal to permanently debar him from providing services in any capacity to a person having an approved or pending drug product application. The proposal also offered Kincaid an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request and 60 days from the date of receipt of the letter to support that request with information sufficient to justify a hearing. In a letter dated June 17, 2015, Kincaid requested a hearing and indicated that the information justifying the hearing would be forthcoming. More than 60 days have passed from the date Kincaid received FDA's letter, and Kincaid has not filed any additional information to support his request.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director of the Office of Scientific Integrity (OSI) has considered Kincaid's request for a hearing. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 21.24(b)).

Because Kincaid has not presented any information to support his hearing request, OSI concludes that Kincaid failed to raise a genuine and substantial issue of fact requiring a hearing. Therefore, OSI denies Kincaid's request for a hearing.

II. Findings and Order

Therefore, OSI, under section 306(a)(2) of the FD&C Act and under the authority delegated, finds that William Ralph Kincaid has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing findings, William Ralph Kincaid is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Kincaid, in any capacity during his period of debarment, will be subject to civil money penalties. See section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6)). If Kincaid, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. See section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7)). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Kincaid during his period of debarment.

Dated: January 10, 2018.

G. Matthew Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2018–00719 Filed 1–17–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Annual Update of the HHS Poverty Guidelines

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice provides an update of the Department of Health and Human Services (HHS) poverty guidelines to account for last calendar year's increase in prices as measured by the Consumer Price Index.

DATES: Applicable beginning January 13, 2018, unless an office administering a program using the guidelines specifies a different applicability date for that particular program.