

Tribal Governments; *Number of Respondents:* 2,029,505; *Total Annual Responses:* 1,033,839,906; *Total Annual Hours:* 18,847,500. (For policy questions regarding this collection contact Charlene Parks at 410-786-8684.)

2. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Health Reimbursement Arrangements and Other Account-Based Group Health Plans; **Use:** On June 20, 2019, the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (collectively, the Departments) issued final regulations titled “Health Reimbursement Arrangements and Other Account-Based Group Health Plans” (84 FR 28888) under section 2711 of the PHS Act and the health nondiscrimination provisions of HIPAA, Public Law 104-191 (HIPAA nondiscrimination provisions). The regulations expand the use of health reimbursement arrangements and other account-based group health plans (collectively referred to as HRAs). In general, the regulations expand the use of HRAs by eliminating the current prohibition on integrating HRAs with individual health insurance coverage, thereby permitting employers to offer individual coverage HRAs to employees that can be integrated with individual health insurance coverage or Medicare. Under the regulations employees will be permitted to use amounts in an individual coverage HRA to pay expenses for medical care (including premiums for individual health insurance coverage and Medicare), subject to certain requirements. This information collection includes provisions related to substantiation of individual health insurance coverage (45 CFR 146.123(c)(5)), the notice requirement for individual coverage HRAs (45 CFR 146.123(c)(6)), and notification of termination of coverage (45 CFR 146.123(c)(1)(iii)). **Form Number:** CMS-10704 (OMB Control Number 0938-1361); **Frequency:** Annually; **Affected Public:** Private Sector, State Governments; **Number of Respondents:** 2,005; **Total Annual**

Responses: 273,492; **Total Annual Hours:** 6,016. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410-786-6650.)

3. Type of Information Collection Request: Extension without change of a currently approved collection; **Title of Information Collection:** Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers; **Use:** The information collection requirements ensure that claimants receive adequate information regarding the plan’s claims procedures and the plan’s handling of specific benefit claims. Claimants need to understand plan procedures and plan decisions in order to appropriately request benefits and/or appeal benefit denials. The information collected in connection with the HHS-administered federal external review process is collected by HHS, and is used to provide claimants with an independent external review. **Form Number:** CMS-10338 (OMB control number: 0938-1099); **Frequency:** Occasionally; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 109,653; **Total Annual Responses:** 4,711; **Total Annual Hours:** 1,195,626. (For policy questions regarding this collection contact Laura Byabazaire at 410-786-6650.)

Dated: November 25, 2019.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019-25861 Filed 11-27-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Intergovernmental Reference Guide (IRG) OMB #0970-0209

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Intergovernmental Reference Guide (IRG) is a centralized and automated repository of state and tribal profiles that contains high-level descriptions of each state and tribal child support enforcement (CSE) program. These profiles provide state, tribal, and foreign country CSE agencies with an effective and efficient method for updating and accessing information needed to process intergovernmental child support cases.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing infocollection@acf.hhs.gov. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Office of Child Support Enforcement (OCSE) is proposing to add a new section (Section O) with six questions pertaining to family violence in the state profile. This will help process intergovernmental cases with family violence and help ensure the safety of children and families. OCSE is also proposing to delete Sections A-L (140 questions) from the tribal profile and create new sections (Sections A-D) with 11 questions regarding case processing. This will assist in the efficient processing of paternity and support obligations.

Respondents: State and tribal CSE agencies.

ANNUAL BURDEN ESTIMATES

Information collection instrument	Total number of respondents	Number of responses per respondent	Average burden hour per response	Annual burden hours
IRG: State Profile Guidance (states and territories)	54	18	0.3	292
IRG: Tribal Profile Guidance	62	18	0.3	335

Estimated Total Annual Burden Hours: 627.

Comments: The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority for the IRG information collection activities is: (1) 42 U.S.C. 652(a)(7), which requires the federal OCSE to provide technical assistance to state child support enforcement agencies to help them establish effective systems for collecting child and spousal support; (2) 42 U.S.C. 666(f), which requires states to enact the Uniform Interstate Family Support Act; (3) 45 CFR 301.1, which defines an intergovernmental case to include cases between states and tribes; (4) 45 CFR 303.7, which requires state CSE agencies to provide services in intergovernmental cases; and (5) 45 CFR 309.120, which requires a tribal child support program to include intergovernmental procedures in its tribal IV-D plan.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019-25851 Filed 11-27-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1537]

James R. Casey: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring James R. Casey for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Casey was

convicted, as defined in the FD&C Act, of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Casey was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of June 30, 2019 (thirty days after receipt of the notice), Mr. Casey had not responded. Mr. Casey's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable November 29, 2019.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM-4029) Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857 or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On January 9, 2019, Mr. Casey was convicted as defined in section 306(l)(1)(B) of the FD&C Act, in the United States District Court for the Eastern District of Virginia, when the court accepted his plea of guilty and entered judgment against him for the offense of conspiracy to violate the Lacey Act in violation of 18 U.S.C. 371 and 16 U.S.C. 3372(d) and 3373(d)(3)(A)(ii).

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Stipulation of Facts incorporated into Mr. Casey's Plea Agreement, filed on September 26, 2018, from on or about 2010 to June 2015, while serving as the owner, operator, and President of Casey's Seafood, Inc. ("the company"), Mr. Casey regularly purchased foreign crab meat from a variety of sources and from a number of different countries. Mr.

Casey also purchased foreign crab meat that had been recalled, returned, or that was approaching or beyond its posted "best used by" dates. Mr. Casey directed company employees to unpack the foreign crab meat from containers and re-pack the crab meat into company containers, all of which were labeled "Product of USA." During that time period, employees routinely emptied foreign crab meat onto tables, comingling crab meat from different sources, and then re-packaged the crab meat into company containers, all of which were labeled "Product of USA." From on or about July 1, 2012 and continuing until June 17, 2015, Mr. Casey caused to be sold at least 367,765 pounds of crab meat falsely labeled "Product of USA" with a total wholesale value of approximately \$4,324,916.

As a result of this conviction, FDA sent Mr. Casey by certified mail on May 22, 2019, a notice proposing to debar him a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) that Mr. Casey's felony conviction of conspiracy to violate the Lacey Act in violation of 18 U.S.C. 371 and 16 U.S.C. 3372(d) and 3373(d)(3)(A)(ii) constitutes conduct relating to the importation into the United States of an article of food because the offense he committed involved falsely labeling crab meat that was imported from a number of foreign countries as "Product of USA."

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Casey should be subject to a 5-year period of debarment. The proposal also offered Mr. Casey 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 advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Casey failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Casey has