contact Jean Close at (410) 786–2804 or Melissa Musotto at (410) 786–6962. For all other issues call (410) 786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *March 13, 2012:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number CMS–R–306 (0938–0833), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 6, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–593 Filed 1–12–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Temporary Assistance for Needy Families/National Directory of New Hires Match Results Report.

OMB No.: 0970–0311.

Description: Section 453(j)(3) of the Social Security Act (the Act) allows for matching between the National Directory of New Hires (maintained by the Federal Office of Child Support Enforcement (OCSE) and State TANF Agencies for purposes of carrying out responsibilities under programs funded under part A of Title IV of the Act. To assist OCSE and the Office of Family Assistance (OFA) in measuring savings to the TANF program attributable to the use of NDNH data matches, the State TANF Agencies have agreed to provide OCSE with a written description of the performance outputs and outcomes attributable to the State TANF Agency's use of NDNH match results. This information will help OCSE demonstrate how the NDNH supports the OCSE's mission and strategic goals.

Respondents: State TANF Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
TANF/NDNH Match Results Report	12	4	0.17	8.16

Estimated Total Annual Burden Hours: 8.16.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Fax: (202) 395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–568 Filed 1–12–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0755]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007

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 February 13, 2012.

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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–5156, *Daniel.Gittleson@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.

Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007—(OMB Control Number 0910–0625)—Extension

Sections 222, 223, and 224 of FDAAA, which were in effect on October 1, 2007, require that device establishment registrations and listings under section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360), including the submission of updated information, be submitted to the Secretary by electronic means, unless the Secretary grants a request for waiver of the requirement because the use of electronic means is not reasonable for the person requesting the waiver. There are approximately 24,000 establishments that are electronically registered as of September 2011.

Section 222 of FDAAA amends sections 510(b) of the FD&C Act to require domestic establishments to register annually during the period beginning October 1 and ending December 31 of each year. Section 222 of FDAAA also amends section 510(i)(1) of the FD&C Act to require foreign establishments to register immediately upon first engaging in one of the covered device activities described under the statute, and in addition, they must also register annually during the time period beginning October 1 and ending December 31 of each year. Further, section 223 of FDAAA amends section 510(j)(2) of the FD&C Act to require establishments to list their devices with FDA annually, during the time period beginning October 1 and ending December 31 of each year.

Under FDAAA, device establishment owners and operators are required to keep their registration and device listing information up-to-date using the Agency's new electronic system. Owners and operators of new device establishments must use the electronic system to create new accounts, new registration records, and new device listings. Section 224 of FDAAA amends section 510(p) of the FD&C Act by allowing an affected person to request a waiver from the requirement to register electronically when the ''use of electronic means'' is not reasonable for the person.

The estimates in table 1 of this document are based on FDA's experience, data from the device registration and listing database, and our estimates of the time needed to complete the previously required forms. We estimate that the time needed to enter registration and listing information electronically using FDA Form 3673 will not differ significantly from the time needed to fill in the paper forms (FDA Forms 2891, 2891a, and 2892) that previously were used for this purpose because the information required is essentially identical.

In addition, under section 224 of FDAAA, device establishment owner/operators, for whom registering and listing by electronic means is not reasonable, may request a waiver from the Secretary. Because a device establishment's owner/operator is required to register and list, they would need only to have access to a computer, Internet, and an email address for registration and listing by electronic means, the Agency did not anticipate receipt of a large number of requests for waivers. From the October through December 2007 timeframe, FDA received fewer than 10 requests for waivers for the requirement to submit registration and listing information electronically. As data for more than 16,000 establishments were received electronically for the same period, these requests amount to less than 1 percent of the total number of establishments that have responded. The number of waiver requests received through fiscal year 2011 has remained consistently less than 1 percent.

Based on information taken from our databases, FDA estimates that there are 21,254 owner/operators who collectively register a total of 24,000 device establishments. The number of respondents listed for section 222 of FDAAA in table 1 of this document is 21,254, which corresponds to the number of owner/operators who annually register. In addition, FDA estimates that 3,504 owner/operators are initial importers who must register their establishments but who, under FDA's existing regulations, are not required to list their devices unless they initiate or develop the specifications for the devices or repackage or relabel the devices. The number of respondents included in table 1 of this document for section 223 of FDAAA is 17,750, which corresponds to the number of owner/operators who annually list one or more devices (21,254 − 3,504 = 17,750).

To calculate the burden estimate for waiver requests under section 224 of FDAAA, we assume as stated previously, that less than 1 percent of the 24,000 total device establishments would request waivers from FDA. This means the total number of waiver requests would probably not exceed 14 requests (24,000 x 0.0006). We also estimate that the one-time burden on these establishments would be an hour of time for a mid-level manager to draft, approve, and mail a letter. In addition, FDA estimates the total number of establishments will increase by 2,162 new establishments each year. Of the 2,162 new registrants each year, we assume that less than 1 percent (i.e., 1) of these will also request waivers each year. The total, therefore, is 14 waiver requests, which could increase by only one additional request each year.

Based on the number of owner operators of foreign establishments reflected in our current database, approximately 8,067 owner operators will spend an hour annually identifying the name, address, telephone and fax numbers, email address, and registration number, if any has been assigned, of any importer of the establishment's devices that is known to the foreign establishment.

Also based on the current number of owner/operators in the FDA database, we estimate that approximately 1,305 owner operators will spend .25 hours each year to identify changes in their U.S. agent's name, address, or phone number to FDA.

The burden estimate for recordkeeping requirements under section 222 of FDAAA in table 2 of this document complies with 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 upon request from FDA. However, it is assumed that some effort will need to be expended for keeping such lists current.

The burden estimate for the recordkeeping requirements under section 223 of FDAAA in table 2 of this document reflect other recordkeeping requirements for devices listed with FDA and the requirement to provide these records upon request from FDA. These estimates are based on FDA experience.

In the **Federal Register** of November 3, 2011 (76 FR 68195), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDAAA Section of the 2007 amendments	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
222 [3]	3673	21,254	1	21,254	0.75	15,941
222 [2]	3673	2,162	1	2,162	0.50	1,081
222 [3]	3673	8,067	1	8,067	1	8,067
222 [3]	3673	1,305	1	1,305	0.25	326
223 [3]	3673	17,750	1	17,750	1	17,750
224 (waiver request) [2]	3673	14	1	14	1	14
224 (waiver request) [3]	3673	1	1	1	2	2
Total						43,181

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.
[3] Annual recurring burden.

TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN[1]

FDAAA Section of the 2007 amendments	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
222 [2]	23,806	1	23,806	0.25	5,952
223 [2]	11,746	4	46,984	0.5	23,492
Total					29,444

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Recurring burden.

Dated: January 9, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–503 Filed 1–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0589]

Anneri Izurieta: 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 (the FD&C Act) debarring Anneri Izurieta for a period of 30 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Ms. Izurieta was convicted of six felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Ms. Izurieta was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of November 4, 2011 (30 days after receipt of the notice), Ms. Izurieta had not responded. Ms. Izurieta's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective January 13, 2012.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, (301) 796–4640.

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, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On May 11, 2011, in the U.S. District Court for the Southern District of Florida, Ms. Izurieta was convicted of one count of conspiracy to smuggle goods into the United States, in violation of 18 U.S.C. 371, and five counts of smuggling goods into the United States, in violation of 18 U.S.C. 545. The U.S. District Court for the Southern District of Florida entered judgment against Ms. Izurieta on July 29, 2011.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the importation into the United States of any food. The factual basis for these convictions is as follows: On or about April 18, 2007, and continuing through on or about December 23, 2010, in violation of 18 U.S.C. 371, Ms. Izurieta knowingly, and with the intent to further the object of the conspiracy, conspired with others to commit an offense against the United States to fraudulently and knowingly import and bring into the United States merchandise contrary to law in violation of 18 U.S.C. 545. Specifically, Ms. Izurieta conspired to distribute and sell imported dairy products that FDA had detained after receiving notice from FDA that the dairy products were suspected to be adulterated.

While serving as president and director of Naver Trading, Ms. Izurieta caused dairy products and other food to be imported from Honduras and Nicaragua. Despite a request from FDA to disclose the location of shipments of dairy products after learning that FDA had slated specific shipments for examination due to concerns of adulteration with *Escherichia coli,*