Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–05880 Filed 3–17–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Federal Strategic Action Plan on Services for Victims of Human Trafficking: Enhancing the Health Care System's Response to Human Trafficking

OMB No.: New Collection

Description:

In 2013, the U.S. Department of Health and Human Services co-chaired an inter-agency process with the Departments of Justice and Homeland Security to create the first Federal Strategic Action Plan on Services for Victims of Human Trafficking in the United States. The Plan addresses the needs for the implementation of coordinated, effective, culturally appropriate and trauma informed care for victims of human trafficking. The purpose of this initiative is to develop a pilot training project that will strengthen the health systems' response to human trafficking in four key ways

1. Increase knowledge about human trafficking among health care providers;

2. Build the capacity of health care providers to deliver culturally appropriate and trauma-informed care to victims of human trafficking;

3. Increase the identification of victims of human trafficking; and

4. Increase services to survivors of human trafficking.

The evaluation will measure immediate outcomes, e.g., from pre-intervention to post-intervention, as well as intermediate outcomes at a 3 month post intervention.

Respondents:

The target audience for training and evaluation will be 200 health care providers from hospitals, clinics, and private health practices. The health care providers will be from federal, state/territorial, and local health departments, the Veterans' Administration, professional associations, and tribal institutions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Pre-training survey	200	1	0.40	80.00
Post-training survey	200	1	0.40	80.00
Email Follow-up	200	1	0.40	80.00
Telephone Follow-up	40	1	0.40	16.00
	.....	.....	.....	256.00

Estimated Total Annual Burden Hours: 256

In compliance with the requirements of Section 506(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. Copies of the proposed collection of information can be obtained and comments may be forwarded 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. Email address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–05824 Filed 3–17–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0878]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Premarket Notification for a New Dietary Ingredient'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On November 25, 2013, the Agency submitted a proposed collection of information entitled ''Premarket Notification for a New Dietary Ingredient'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0330. The approval expires on February 28, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: March 12, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–05876 Filed 3–17–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0373]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 30, 2013, the Agency submitted a proposed collection of information entitled ''Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0541. The approval expires on February 28, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: March 12, 2014.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2014–05848 Filed 3–17–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0223]

Humanitarian Device Exemption: Questions and Answers; Draft Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Humanitarian Device Exemption (HDE): Questions and Answers.'' This draft guidance answers commonly asked questions about humanitarian use devices (HUDs) and HDE applications. This guidance document reflects changes to the HDE program as a result of the Food and Drug Administration Safety and Innovation Act (FDASIA). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 16, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Humanitarian Device Exemption (HDE): Questions and Answers'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION

I. Background

This draft guidance answers commonly asked questions about HUDs and HDE applications authorized under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)). Section 613 of FDASIA (Pub. L. 112–144), signed into law on July 9, 2012, amended section 520(m) of the FD&C Act. This draft guidance document reflects the changes in the HDE program as a result of FDASIA. Upon issuance as a final guidance document, this guidance will replace the existing HDE guidance entitled ''Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff—Humanitarian Device Exemption Regulation: Questions and Answers,'' issued on July 8, 2010, which was developed and issued prior to the enactment of FDASIA.

HUDs approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit), except in certain circumstances. FDASIA expands the types of HDE-approved HUDs that are eligible to be sold for profit, subject to restrictions in section 520(m)(6) of the FD&C Act.

FDASIA also amends the definition of the annual distribution number (ADN). Under section 520(m)(6) of the FD&C Act, if FDA makes a determination that a HUD meets certain conditions, the HUD is permitted to be sold for profit after receiving HDE approval as long as the number of devices distributed in any