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[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](mailto: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,
PRASStaff@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](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