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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](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, PRASStaff@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