alternatives. Scoping comment cards will be provided at the Open House portion of the meeting for those who need to leave early but who wish to make a comment for the record. At approximately 8 p.m., HHS/CDC will give a brief overview of the current conditions and the planning and EIS processes. Individuals staying for this portion of the Scoping Meeting may make verbal statements or use a Scoping comment card. A stenographer will record this portion of the Scoping Meeting. An American Sign Language Interpreter will be available at both portions of the Scoping Meeting. The agenda is subject to change without notice. A transcript of the meeting and all comments received at the meeting will be posted to the public docket at *www.regulations.gov*.

Roybal Campus Security Guidelines

The Edward R. Roybal Campus is the headquarters of the U.S. Centers for Disease Control and Prevention and is located at 1600 Clifton Road NE., Atlanta, Georgia. The meeting is being held in a Federal government building; therefore, Federal security measures are applicable.

In planning your arrival time, please take into account the need to park and clear security. All visitors must enter the Roybal Campus through the entrance on Clifton Road; the guard force will direct visitors to the designated parking area. Visitors must present government issued photo identification (e.g., a valid Federal identification badge, state driver's license, state non-driver's identification card, or passport). Non-United States citizens must present a valid passport, visa, Permanent Resident Card, or other type of work authorization document. All persons entering the building must pass through a metal detector. Visitors will be issued a visitor's ID badge at the entrance to Building 19 and will be escorted in groups of 5–10 persons to the meeting room. All items brought to HHS/CDC are subject to inspection.

Dated: December 11, 2012.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2012–30276 Filed 12–14–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Understanding the Dynamics of Disconnection from Employment and Assistance.

OMB No.: New Collection.

Description: The Office of Planning, Research and Evaluation, Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity to improve understanding of low-income individuals and families who are disconnected from employment and from public assistance and particularly those not receiving cash assistance through the Temporary Assistance for Needy Families (TANF) program. ACF is proposing to use a discussion guide to collect qualitative information. The guide will be used to interview respondents in order to learn about their experiences with disconnection. Topics will include recent employment and reasons for not working; use of public benefit programs and reasons for using or not using specific benefits; their financial circumstances and material well-being including the stability and sources of income, housing and living arrangements; their coping strategies for addressing their circumstances; and their views on potential pathways to improve their financial and material well-being.

Information will be collected in two sites with relatively high concentrations of low-income families: Los Angeles, California and Southeast Michigan. Respondents will be sampled from two existing longitudinal surveys in those sites: The Best Start Los Angeles Pilot Community Evaluation, currently led by the Urban Institute's Health Policy Center and the Center for Healthier Children, Families and Communities at the University of California Los Angeles (UCLA), and the Michigan Recession and Recovery Study OIRTO, conducted by the National Poverty Center of the University of Michigan.

Respondents: Low-income women who have resident children and who are neither employed nor receiving TANF or Supplemental Security Income (SSI) for themselves. Women who are currently employed or receiving TANF may be included in the study if they experienced at least six months of unemployment in the past two years, had a child Lid were unmarried during the period of unemployment, and were not receiving TANF at the time.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Advertisement Script (LA)	300	1	0.1	30
Telephone Recruitment script and Screener (LA)	100	1	0.25	25
Follow-up Telephone Script to Schedule Interview (LA)	36	1	0.05	2
Consent Form for Interviews (LA)	36	1	0.2	7
Receipt of Payment Form (LA)	36	1	0.03	1
Consent Form for Linking Data (LA)	36	1	0.08	3
Telephone Recruitment Script and Screener (MI)	35	1	0.25	9
Consent Form for Interviews (MI)	30	1	0.2	6
Conversation Guide (LA and MI)	66	90	1.5	99

Estimated Total Annual burden hours: 182.

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: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@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, Email: *OIRA SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2012–30155 Filed 12–14–12; 8:45 am]

BILLING CODE 4184–09–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1203]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information To Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information to accompany humanitarian device exemption (HDE) applications and the collection of information regarding the annual distribution number (ADN).

DATES: Submit either electronic or written comments on the collection of information by February 15, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information To Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements (formerly: Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators and FDA Staff Humanitarian Device Exemption Regulation: Questions and Answers)—(OMB Control Number 0910–0661)—Revision

Under section 520(m) (21 U.S.C. 360j(m)) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), the FDA is authorized to exempt a humanitarian use device (HUD) from the effectiveness requirements in sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnose the disease or condition; (3) the device will not expose patients to an unreasonable or significant risk of illness or injury; and (4) the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

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 narrow circumstances. Section 613 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112–144), signed into law on July 9, 2012, amended section 520(m) of the FD&C Act. Under section 520(m)(6)(A)(i) of the FD&C Act, as amended by FDASIA, a HUD approved under an HDE is eligible to be sold for profit if the device meets the following criteria:

- The device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or
- The device is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

Section 520(m)(6)(A)(ii) of the FD&C Act, as amended by FDASIA, provides that the Secretary of Health and Human Services (the Secretary) will assign an ADN for devices that meet the eligibility criteria to be permitted to be sold for profit. The ADN is defined as the number of devices ''reasonably needed to treat, diagnose, or cure a population of 4,000 individuals in the United States,'' and therefore shall be based on the following information in a HDE application: the number of devices reasonably necessary to treat such individuals.