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.

Section 520(m)(6)(A)(iii) of the FD&C Act

(*http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/default.htm*) provides that an HDE holder immediately notify the Agency if the number of devices distributed during any calendar year exceeds the ADN. Section 520(m)(6)(C) of the FD&C Act provides that an HDE holder may petition to modify the ADN if additional information arises.

On August 5, 2008, FDA issued a guidance entitled ''Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff—Humanitarian Device Exemption (HDE) Regulation: Questions and Answers'' (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf*). The guidance was developed and issued prior to the enactment of FDASIA, and certain sections of this guidance may no longer be current as a result of FDASIA. The Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research are currently working on a draft HDE guidance, that when finalized, will represent the FDA's current thinking on this topic.

FDA is requesting OMB approval for the collection of information required under the statutory mandate of sections 515A (21 U.S.C. 360e–1) and 520(m) of the FD&C Act as amended.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/section of FD&C Act (as amended) or FDASIA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pediatric Subpopulation and Patient Information—515A(a)(2) of the FD&C Act	6	1	6	100	600
Exemption from Profit Prohibition Information—520(m)(6)(A)(i) and (ii) of the FD&C Act	3	1	3	50	150
Request for Determination of Eligibility Criteria—613(b) of FDASIA	2	1	2	10	20
ADN Notification—520(m)(6)(A)(iii) of the FD&C Act	1	1	1	100	100
ADN Modification—520(m)(6)(C) of the FD&C Act	5	1	5	100	500
Total					1,370

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

FDA based these estimates on the number of original HDE applications received in the period between October 1, 2008, and September 30, 2011. During that time, FDA's Center for Devices and Radiological Health received 19 original HDE applications, or about 6 per year. FDA estimates that for each year we will receive six HDE applications and that three of these applications will be indicated for pediatric use. The request for determination of eligibility criteria is new under section 613(b) of FDASIA. We estimate that we will receive approximately two such requests per year. Historically, no companies have exceeded the ADN; and under FDASIA the ADN has expanded to a minimum of 4,000. Therefore, FDA estimates that very few or no HDE holders will notify the Agency that the number of devices distributed in the year has exceeded the ADN. FDA estimates that five HDE holders will petition to have the ADN modified due to additional information on the number of individuals affected by the disease or condition.

The draft guidance refers also to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A, B, and C, have been approved under OMB control number 0910–0231; the collection of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; and the collection of information requirements in 21 CFR 10.30 have been approved under OMB control number 0910–0183.

Dated: December 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30275 Filed 12–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0298; Formerly Docket No. 2004D–0499]

Compliance Policy Guide; Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs; Notice To Extend Expiration Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of expiration date.

SUMMARY: The Food and Drug Administration (FDA) is extending the expiration date of compliance policy guide (CPG) Sec. 400.210 entitled ''Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs'' to December 31, 2014.

FOR FURTHER INFORMATION CONTACT: Connie Jung, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4268, Silver Spring, MD 20993–0002, 301–796–3130.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 17, 2004 (69 FR 67360), FDA announced the