ESTIMATED ANNUALIZED BURDEN TO RESPONDENTS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|---|---|---|---|
| State Domestic Violence Coalition Executive Director. | DELTA FOCUS Survey ..... | 10 | 1 | 1 | 10 |
| State Domestic Violence Coalition Project Coordinator. | DELTA FOCUS Survey ..... | 10 | 1 | 1 | 10 |
| Coordinated Community Response Project Coordinator. | DELTA FOCUS Survey ..... | 19 | 1 | 1 | 19 |
| State Domestic Violence Coalition Empowerment Evaluator. | DELTA FOCUS Survey ..... | 10 | 1 | .50 | 5 |
| Total ..... | ..... | ..... | ..... | ..... | 44 |

Dated: March 28, 2013.

**Ron A. Otten,**

*Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2013–07741 Filed 4–2–13; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–1203]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by May 3, 2013.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0661. Also include the FDA 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:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### 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) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)), 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) (Pub. L. 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/FederalFoodDrugandCosmeticAct FDCAct/FDCActChapterVDrugs andDevices/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.

In the **Federal Register** of December 17, 2012 (77 FR 74667), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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: March 29, 2013.

**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2013–07696 Filed 4–2–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–D–0362]**

### Draft Guidance for Industry and Food and Drug Administration Staff; Glass Syringes for Delivering Drug and Biological Products: Technical Information To Supplement International Organization for Standardization Standard 11040–4; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry and FDA staff entitled ''Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040–4.'' These supplemental data are necessary for FDA to ensure the safe and effective use of glass syringes that comply with the ISO 11040–4 standard when connected to devices (''connecting devices'') that comply with the ISO 594–2 standard.