automatically will be evaluated. Other commenters questioned FDA's implementation and Congress' intent of the FSPTCA and its definition of substantial equivalence and new products.

(Response 4) The FD&C Act as amended by the FSPTCA establishes the definition of ''new tobacco product'' and the premarket pathways, of which substantial equivalence is one. FDA believes the information collection estimates are appropriate and reflect estimates of the time it would take to put together and report the information needed in a substantial equivalence submission required by the statute.

(Comment 5) One commenter stated that the commenter believes that substantial equivalence reports should be exempt from environmental assessment requirements.

(Response 5) The National Environmental Policy Act and FDA implementing regulations require environmental assessment requirements.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| FD&C Act sections | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 905(j)(1)(A)(i) and 910(a) | 1,000 | 1 | 1,000 | 360 | 360,000 |

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

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA's expectations regarding the tobacco industry's use of the section 905(j) pathway to market their products. Table 1 describes the annual reporting burden as a result of the implementation of the substantial equivalence requirements of sections 905(j) and 910(a) of the FD&C Act (21 U.S.C. 387j(a)). FDA estimates that it will receive 1,000 section 905(j) reports each year and that it will take a manufacturer approximately 360 hours to prepare a report of substantial equivalence for a new tobacco product. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 360,000 hours.

Dated: June 4, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–13434 Filed 6–9–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0619]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices

**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 extension 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 collection requirements for humanitarian use devices (HUDs).

**DATES:** Submit either electronic or written comments on the collection of information by August 11, 2014.

**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:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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 extension 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.

**Medical Devices; Humanitarian Use Devices—21 CFR 814 (OMB Control Number 0910–0332)—Extension**

This collection of information implements the HUD provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)) and subpart H, part 814 (21 CFR part 814). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of 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 an exemption is granted because there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose the disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury with the probable benefit to health from using the device outweighing the risk of injury or illness from its use. This takes into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

The number of respondents in tables 1, 2, and 3 of this document are an average based on data for the previous 3 years, i.e., fiscal years 2011 through 2013. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 32 respondents with approved HUD applications. Likewise, under § 814.126(b)(2) in table 2, the number of recordkeepers is 247.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity/21 CFR Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Request for HUD designation—814.102 | 16 | 1 | 16 | 40 | 640 |
| Humanitarian device exemption (HDE) application—814.104 | 7 | 1 | 7 | 320 | 2,240 |
| HDE amendments and resubmitted HDEs—814.106 | 14 | 5 | 70 | 50 | 3,500 |
| HDE supplements—814.108 | 112 | 1 | 112 | 80 | 8,960 |
| Notification of withdrawal of an HDE—814.116(e)(3) | 8 | 1 | 8 | 1 | 8 |
| Notification of withdrawal of institutional review board approval—814.124(b) | 3 | 1 | 3 | 2 | 6 |
| Periodic reports—814.126(b)(1) | 32 | 1 | 32 | 120 | 3,840 |
| Total | | | | | 19,194 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Activity/21 CFR Section | Number of recordkeepers | Number of records per recordkeeping | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| HDE Records—814.126(b)(2) | 247 | 1 | 247 | 2 | 494 |

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| Activity/21 CFR Section | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| Notification of emergency use—814.124(a) | 22 | 1 | 22 | 1 | 22 |

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

Dated: June 4, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–13435 Filed 6–9–14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–E–1234]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; STENDRA

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for STENDRA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit electronic comments to *http://*