

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus groups .....	725	1	725	1.75 .....	1,269
Customer comment cards/forms .....	1,200	1	1,200	0.25 (15 minutes) .....	300
Small discussion groups .....	725	1	725	1.75 .....	1,269
Customer satisfaction surveys .....	6,450	1	6,450	0.33 (20 minutes) .....	2,129
Total .....					4,967

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 16, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–22461 Filed 9–19–14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2013–N–1164]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Exceptions Or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile” 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** On July 22, 2014, the Agency submitted a proposed collection of information entitled “Exceptions Or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile” 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 0910–0614. The

approval expires on August 31, 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: September 16, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2007–D–0369]

#### Bioequivalence Recommendations for Estradiol Vaginal Cream; Draft Guidance for Industry; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled “Draft Guidance on Estradiol.” The guidance provides specific recommendations on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for estradiol vaginal cream. This draft guidance is a revised version of a previously issued draft guidance of the same subject.

**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 comments 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 November 21, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993.

Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.

**FOR FURTHER INFORMATION CONTACT:** Kris André, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1615, Silver Spring, MD 20993, 240–402–7800.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and to provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of revised draft BE recommendations for estradiol vaginal cream.

ANDA 086069 for Estrace Cream (estradiol vaginal cream, USP, 0.01%) was initially approved by FDA in January 1984. In August 2009, FDA issued a draft guidance for industry on BE recommendations for generic estradiol vaginal cream. FDA is now issuing a revised version of the draft BE recommendations for estradiol vaginal cream. This revised draft guidance changes the recommendation for an in

vivo pharmacokinetic BE study from a parallel study design to a crossover study design, but is the same in all other respects.

In January 2005, Warner Chilcott, Inc., submitted a citizen petition requesting that FDA stay final approval and/or the effective date of final approval of any ANDA that relies on Estrace Cream as the reference listed drug unless the ANDA meets certain requirements related to demonstrating bioequivalence. FDA reviewed the issues raised in the petition and is responding to the petition (see FDA letter to Warner Chilcott, Inc, Docket No. FDA-2005-P-0006, available at <http://www.regulations.gov>).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for estradiol vaginal cream. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 16, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0001]

#### Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on December 12, 2014, from 8 a.m. to 6 p.m.

*Location:* Holiday Inn Washington-College Park, 10000 Baltimore Ave., College Park, MD 20740. The hotel phone number is 1-800-315-2621.

*Contact Person:* S.J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1643, Silver Spring MD 20993-0002, [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov), 301-796-7047, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On December 12, 2014, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application for the Superior InterSpinous Spacer device sponsored by Vertiflex Incorporated. The proposed Indication for Use for the Superior InterSpinous Spacer device, as stated in the PMA, is as follows: the Superior InterSpinous Spacer (the Superior ISS) is intended to treat skeletally mature patients suffering from pain, numbness,

and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, confirmed by X-ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The Superior ISS is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain. The Superior ISS may be implanted at one or two adjacent lumbar (L) levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 13, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on December 12, 2014. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 5, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 6, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.