

*Matters to be discussed:* Diabetes, cardiovascular disease, and promoting health equity. Topics are subject to change.

*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.

All meeting attendees must RSVP by the dates outlined under *Meeting Accessibility*. 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. Your car may be searched, and the guard force will then direct visitors to the designated parking area. Upon arrival at the facility, 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 complete the required security paperwork prior to the meeting date and must present a valid passport, visa, Permanent Resident Card, or other type of work authorization document upon arrival at the facility. 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 may be escorted to the meeting room. All items brought to HHS/CDC are subject to inspection.

Dated: September 17, 2014.

**Ron A. Otten,**

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

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**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0487]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Food and Drug Administration Service Delivery

**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 (PRA).

**DATES:** Fax written comments on the collection of information by October 22, 2014.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0697. Also include the FDA 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](mailto:PRAStaff@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.

#### Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery—(OMB Control Number 0910-0697)—Extension

The information collection activity will garner qualitative customer and stakeholder feedback in an efficient,

timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback, FDA means information that provides useful insight on perceptions and opinions, not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insight into customer or stakeholder perceptions; experiences and expectations; provide an early warning of issues with service; or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. This information collection will allow for ongoing collaborative and actionable communications among the FDA and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address the following: The target population to which the generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, the methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

In the **Federal Register** of April 29, 2014 (79 FR 23980), 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<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.*

[FR Doc. 2014–22452 Filed 9–19–14; 8:45 am]

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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