TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

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

[1] 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]

BILLING CODE 4164–01–P

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