

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
202.1(e)(6)—Waiver request to FDA	1	1	1	12	12
202.1(j)(1)—Submission of advertisement to FDA for prior approval	1	1	1	2	2
202.1(j)(1)(iii)—Providing a program to FDA for assuring that adverse information about the drug will be publicized	1	1	1	12	12
202.1(j)(4)—Voluntarily submitting the advertisement to FDA prior to publication for comment	113	6	678	20	13,560
Total					13,586

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
202.1—Advertisements prepared in accordance with § 202.1	541	46.5	25,157	400	10,062,800
202.1(j)(1)—Including information about the drug's fatalities or serious damage in the advertisement	1	1	1	40	40
Total					10,062,840

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

Dated: May 30, 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–N–0444]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups as Used by the Food and Drug Administration (All Food and Drug Administration-Regulated Products)

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 July 7, 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 *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0497. 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*.

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.

Focus Groups as Used by the Food and Drug Administration (All FDA-Regulated Products)—(OMB Control Number 0910–0497)—Extension

FDA conducts focus group interviews on a variety of topics involving FDA-regulated products, including drugs, biologics, devices, food, tobacco, and veterinary medicine.

Focus groups provide an important role in gathering information because they allow for a more indepth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain consumer information that is useful for developing variables and measures for quantitative studies,
- To better understand consumers' attitudes and emotions in response to topics and concepts, and
- To further explore findings obtained from quantitative studies.

FDA will use focus group findings to test and refine ideas but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

In the **Federal Register** of February 18, 2014 (79 FR 9222), 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	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus Group Interviews	1,440	1	1,440	1.75	2,520

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

Annually, FDA projects about 20 focus group studies using 160 focus groups with an average of 9 persons per group, and lasting an average of 1.75 hours each. FDA is requesting this burden for unplanned focus groups so as not to restrict the Agency's ability to gather information on public sentiment of its proposals in its regulatory and communications programs.

Dated: May 30, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0424]

Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 invites comments on reporting requirements contained in existing FDA regulations governing temporary marketing permit applications.

DATES: Submit either electronic or written comments on the collection of information by August 4, 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, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite 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.

Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i) (OMB Control Number 0910-0133—Extension)

Section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity for food "[w]henver . . . such action will promote honesty and fair dealing in the interest of consumers. . . ." Under section 403(g) of the FD&C Act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) enables the Agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions and standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

We estimate the burden of this collection of information as follows: