TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and Form FDA 3779	No. of Respondents	No. of Responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting violations of the FD&C Act, as amended by the Tobacco Control Act, by telephone, Internet form, mail, smartphone application, or email..	400	2	800	0.25 (15 minutes)	200

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

FDA estimates that submitting the information (by telephone, Internet, mail, smartphone application, or email) will take 0.25 hours (i.e., 15 minutes) per response. FDA estimates the number of annual respondents to this collection of information will be 400, who will each submit 2 reports by telephone, Internet, mail, smartphone application, or email. This estimate is based on the rate of reporting through Form FDA 3779, reports received from FDA's toll-free telephone number and email address, and FDA experience. Each report is expected to take 0.25 hours to complete and submit; therefore, total burden hours for this collection of information is estimated to be 200 hours (800 responses x 0.25 hours per response). The total burden hours for this collection have decreased by 50 hours (from 250 to 200) because the number of estimated respondents decreased from 1,000 to 400, and the annual responses are expected to drop from 1,000 to 800 annually. Based on past submissions to FDA, the number of estimated annual respondents is expected to decrease from 1,000 to 400 and each respondent's number of submissions is expected to increase from 1 to 2 annually. Therefore, the number of responses are expected to decrease from 1,000 to 800 annually (400 respondents x 2 responses).

Dated: February 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03381 Filed 2–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0823]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Over-the-Counter Human Drugs; Labeling Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Over-the-Counter Human Drugs; Labeling Requirements'' 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 20, 2013; the Agency submitted a proposed collection of information entitled ''Over-the-Counter Human Drugs; Labeling Requirements'' 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 0910–0340. The approval expires on January 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: February 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03348 Filed 2–14–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0168]

Agency Information Collection Activities; Proposed Collection; Comment Request; Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled ''Disclosure Regarding Additional Risks in Direct-to-Consumer (DTC) Prescription Drug Television (TV) Advertisements (Ads).'' This study will investigate the impact of limiting the risks presented in DTC prescription drug television ads to those that are serious and actionable, and including a disclosure to alert consumers that there are other product risks not disclosed in the ad.

DATES: Submit either electronic or written comments on the collection of information by April 21, 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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 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.

Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements—(OMB Control Number 0910—NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

Prescription drug advertising regulations (21 CFR 202.1) require that broadcast (TV or radio) advertisements present the product's major risks in either audio or audio and visual parts of the advertisement; this is often called the ''major statement.'' There is concern that as currently implemented in DTC ads, the major statement is often too long, which may result in reduced consumer comprehension, minimization of important risk information and, potentially, therapeutic noncompliance due to fear of side effects. At the same time, there is concern that DTC TV ads do not include adequate risk information or leave out important information. These are conflicting viewpoints. A possible resolution is to limit the risks in the major statement to those that are serious and actionable, and include a disclosure to alert consumers that there are other product risks not included in the ad. For example, the disclosure could be, ''This is not a full list of risks and side effects. Talk to your doctor and read the patient labeling for [drug name] before starting it.'' The Office of Prescription Drug Promotion (or we) plans to investigate the effectiveness of this ''limited risks plus disclosure'' strategy through empirical research.

Our hypothesis is that, relative to inclusion of the full major statement, providing limited risk information along with the disclosure about additional risks will promote improved consumer perception and understanding of serious and actionable drug risks. We will also investigate other questions such as whether overall drug risk and benefit perceptions are affected by these changes. To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described below, we will have sufficient power to detect small- to medium-sized effects in the main study.

Participants will be consumers who self-identify as having been diagnosed with one of three possible medical conditions. All participants will be 18 years of age or older. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Recruitment and administration of the study will take place over the Internet. Participation is estimated to take approximately 30 minutes.

Within medical condition, participants will be randomly assigned to view one of four possible versions of an ad, as depicted in table 1 below. One version will present the full major statement without the disclosure regarding additional risks (conditions C, G, and K). This version will implement existing ads in the marketplace. Stimuli variations for the other three versions will be achieved by replacing the audio track of the original ad with the revised risk and disclosure statements described above. Thus, a second version of the ad will include the full major statement plus the disclosure about additional risks (conditions A, E, and I). A third version will include an abbreviated statement of risks without the disclosure about additional risks (conditions G, H, and L). The fourth version will include an abbreviated statement of risks as well as the disclosure about additional risks (conditions B, F, and J).

After viewing the ad, participants will respond to questions about information in the ad. Preliminary measures are designed to assess perception and understanding of product risks and benefits; perception and understanding of the disclosure about additional risks; perceptions of product quality; intention to seek more information about the product; and perceptions of trust/skepticism regarding product claims and the sponsor. The questionnaire is available upon request.

TABLE 1—STUDY DESIGN

Medical condition	Disclosure regarding additional risks	Major statement	
		Version 1	Version 2
1	Present	A	B
	Absent	C	D
2	Present	E	F
	Absent	G	H
3	Present	I	J
	Absent	K	L

NOTE: Version 1 = current major statement; Version 2 = abbreviated major statement.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Disclosure regarding additional risks in DTC prescription drug TV ads	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pilot study screener	3300	1	3300	0.03 (2 minutes)	99
Main study screener	10000	1	10,000	0.03 (2 minutes)	300
Pilot study	500	1	500	1	500
Main study	1500	1	1500	0.50 (30 minutes)	750
Total					1649

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

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03390 Filed 2–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0588]

Agency Information Collection Activities; Proposed Collection; Comment Request; 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 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 the information collection requirements related to the exceptions or alternatives to labeling requirements for products held by the Strategic National Stockpile (SNS).

DATES: Submit either electronic or written comments on the collection of information by April 21, 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.

Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile—(OMB Control Number 0910–0614)—Extension

Under the Public Health Service Act (PHS Act), the Department of Health and Human Services stockpiles medical products that are essential to the health security of the nation (see PHS Act, 42 U.S.C. 247d–6b). This collection of medical products for use during national health emergencies, known as the SNS, is to ''provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.''

It may be appropriate for certain medical products that are or will be held in the SNS to be labeled in a manner that would not comply with certain FDA labeling regulations given their anticipated circumstances of use in an emergency. However, noncompliance with these labeling requirements could render such products misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

Under §§ 201.26, 610.68, 801.128, and 809.11 (21 CFR 201.26, 610.68, 801.128, and 809.11), the appropriate FDA Center Director may grant a request for an exception or alternative to certain regulatory provisions pertaining to the labeling of human drugs, biological products, medical devices, and in vitro diagnostics that currently are or will be included in the SNS if certain criteria are met. The appropriate FDA Center Director may grant an exception or alternative to certain FDA labeling requirements if compliance with these labeling requirements could adversely