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]

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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.