

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN¹

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
501.22(k); labeling of color additive or lake of color additive; labeling of color additives not subject to certification.	3,120	0.8292	2,587	0.25 (15 minutes).	647

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: February 26, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04461 Filed 3–3–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3077]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Obtaining Information To Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled “Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On December 18, 2020, the Agency submitted a proposed collection of information entitled “Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities” 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 0910–0883. The approval expires on January 31, 2022. A copy of the supporting statement for this information collection is available on the internet at <https://www.reginfo.gov/public/do/PRAMain>.

Dated: February 26, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1228]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Study of Multiple Indications in Direct-to-Consumer Television Advertisements

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: Submit written comments (including recommendations) on the collection of information by April 5, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or

by using the search function. The title of this information collection is “Study of Multiple Indications in Direct-to-Consumer Television Advertisements.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRASStaff@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.

Study of Multiple Indications in Direct-to-Consumer 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 (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.

The Office of Prescription Drug Promotion’s (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP’s research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health.

Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: (1) Advertising features, including content and format; (2) target populations; and (3) research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and disease and product characteristics impact the communication and