Format and Content Requirements for Over-the-Counter Drug Product Labeling—21 CFR Part 201

OMB Control Number 0910–0340—Extension

This information collection supports FDA regulations at § 201.66 (21 CFR 201.66), which establish standardized content and format requirements for the labeling of all marketed OTC drug products. The regulations set forth the content and format requirements for the Drug Facts portion of labels on OTC drug products. These regulations require OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features.

Currently marketed OTC drug products are already required to comply with these labeling requirements and will incur no further burden to comply with Drug Facts labeling requirements in § 201.66. Labeling modifications already required to be in Drug Facts format are ''usual and customary'' as part of routine redesign practice, thus they do not create additional burden within the meaning of the PRA.

Therefore, burden for this information collection is that which is necessary to comply with the labeling requirements in § 201.66, applicable to new OTC drug products and OTC sunscreen drug products introduced to the marketplace under new drug applications, abbreviated new drug applications, or an OTC drug monograph. New OTC drug products must comply with the labeling requirements in § 201.66 as they are introduced to the marketplace.

Based on our electronic drug registration and listing database, we estimate that approximately 10,463 new OTC drug product stock keeping units (SKUs) are introduced to the marketplace each year. We estimate that these SKUs are marketed by 1,416 manufacturers. We estimate that the preparation of labeling for new OTC drug products requires 12 hours to prepare, complete, and review prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is 94,296 hours.

All currently marketed sunscreen products are required to comply with the Drug Facts labeling requirements in § 201.66, so they will incur no further burden under the information collection provisions in the regulation. However, a new OTC sunscreen drug product, like any new OTC drug product, will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. We estimate, based on our electronic drug registration and listing database, that 5,253 new SKUs of OTC sunscreen drug products will be marketed each year. We estimate that these 5,253 SKUs will be marketed by 294 manufacturers. We estimate that 12 hours will be spent on each label. This is reflected in table 1, row 1.

When determining the burden for § 201.66, it is also important to consider exemptions or deferrals of the regulation allowed products under § 201.66(e). We receive very few requests for exemptions or deferrals. We also estimate that a request for deferral or exemption requires 24 hours to complete. This is reflected in table 1, row 2.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosure	Average burden per disclosure	Total hours
§ 201.66(c) and (d) for new OTC drug products	855	9.19	7,858	12	94,296
§ 201.66(e)	1	1	1	24	24
Total					94,320

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

Our estimated burden for the information collection reflects an overall increase of 82,797 hours and a corresponding increase of 6,898 disclosures. This increase corresponds with data obtained from our database.

Dated: June 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12996 Filed 6–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2683]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 a generic clearance to collect information to support social and behavioral research used by FDA about drug products.

DATES: Submit either electronic or written comments on the collection of information by August 19, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 19, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 19, 2019. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2683 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Data to Support Social and Behavioral Research as Used by the Food and Drug Administration.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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

Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910–0847—Extension

Understanding patients, consumers, and healthcare professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decisionmaking processes and communications impacting various stakeholders. The methods used to achieve these goals include individual in-depth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and focus group interviews. The methods used serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative and quantitative research tool, and have two major purposes:

1. To obtain information that is useful for developing variables and measures for formulating the basic objectives of social and behavioral research and

2. To assess the potential effectiveness of FDA communications, behavioral interventions and other materials in reaching and successfully communicating and addressing behavioral change with their intended audiences.

FDA will use these methods to test and refine its ideas and to help develop communication and behavioral

strategies research, 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.

FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner, and any other Centers or Offices will use this mechanism to test communications and social and behavioral methods about regulated drug products on a variety of subjects related to consumer, patient, or healthcare professional perceptions, beliefs, attitudes, behaviors, and use of drug and biological products and related materials including, but not limited to, social and behavioral research, decision-making processes, and communication and behavioral change strategies.

Annually, FDA projects about 45 social and behavioral studies using the variety of test methods listed in this document. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

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
Interviews/Surveys	2,520	14.6	36,792	.25 (15 minutes).	9,198

[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: June 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13001 Filed 6–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: The Teaching Health Center Graduate Medical Education Program Eligible Resident/Fellow FTE Chart, OMB No. 0915–0367—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than August 19, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail them to HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Teaching Health Center Graduate Medical Education (THCGME) Program Eligible Resident/Fellow FTE Chart, OMB No. 0915–0367—Extension.

Abstract: The Teaching Health Center Graduate Medical Education (THCGME) Program, Section 340H of the Public Health Service Act, was established by Section 5508 of Public Law 111–148. The Bipartisan Budget Act of 2018 (Pub. L. 115–123) provided continued funding for the THCGME Program. The THCGME Program awards payment for both direct and indirect expenses to support training for primary care residents in community-based ambulatory patient care settings. The THCGME Program Eligible Resident/Fellow Full-Time Equivalents (FTE) Chart, published in the THCGME Notice of Funding Opportunity (NOFO), is a means for determining the number of eligible resident/fellow FTE's in an applicant's primary care residency program.

Need and Proposed Use of the Information: THCGME Program Eligible Resident/Fellow FTE Chart requires applicants to provide: (a) Data related to the size and/or growth of the residency program over previous academic years, (b) the number of residents enrolled in the program during the baseline academic year, and (c) a projection of the program's proposed expansion over the next five academic years. It is imperative that applicants complete this chart to quantify the total supported residents. THCGME funding is used to support an expanded number of residents in a residency program, to establish a new residency training program, or to maintain filled positions at existing programs. Utilization of a chart to gather this important information has decreased the number of errors in the eligibility review process resulting in a more accurate review and funding process, and comports with the regulatory requirement imposed by 45 CFR 75.206(a) ''*Standard application requirements, including forms for applying for HHS financial assistance, and state plans.*''

Likely Respondents: Teaching Health Centers applying for THCGME funding through a THCGME NOFO process, which may include new applicants and existing awardees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search