posted on *https://www.regulations.gov*. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: Written comments must be received on or before September 22, 2021.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the September 22–23, 2021, ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EDT, September 20, 2021, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by 12:00 p.m., EDT, September 21, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–20473 Filed 9–17–21; 11:15 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0952]

Final Administrative Orders for Over-the-Counter Monographs; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability on its website of certain final administrative orders (final orders), including for over-the-counter (OTC) drug monographs, that were deemed to be final orders by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which added a new section to the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA is also announcing the process for making these final orders available. Finally, FDA is announcing its plan for withdrawing regulations that established final OTC drug monographs prior to the passage of the CARES act, and withdrawing or making technical changes to the procedures governing the OTC drug review.

DATES: The announcement of the availability on FDA's website of certain final orders as deemed by section 505G of the FD&C Act and other actions related to section 505G is published in the **Federal Register** on September 21, 2021.

ADDRESSES: You may view the final orders in the OTC *Monographs@FDA* portal at *https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm.*

- *Instructions:* For access to the final orders, go to *https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm.* Under the ''Administrative Orders'' banner, click on the desired link under the ''Order ID'' heading and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Helen Lee, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6848.

SUPPLEMENTARY INFORMATION:

I. Background

On March 27, 2020, the CARES Act was signed into law. The CARES Act includes provisions that govern the way certain OTC drugs are regulated in the United States. In particular, the CARES Act added section 505G to the FD&C Act (21 U.S.C. 355g), which reforms and modernizes the OTC drug review process that was established in 1972. Under the OTC drug review, OTC drug monographs (also referred to as OTC monographs) for different therapeutic categories are established. OTC drugs are generally recognized as safe and effective (GRASE) if they meet the conditions of an OTC monograph, including the specified active ingredients, uses (indications), doses, routes of administration, labeling, and testing, along with other applicable requirements.

A. Regulatory Framework for OTC Monograph Drugs Prior to the Passage of the CARES Act

Prior to passage of the CARES Act, OTC monographs were established, revised, and amended using the rulemaking process set out by the Administrative Procedure Act in 21 U.S.C. 553. Final OTC monographs (final monographs) were codified in regulations under title 21 of the CFR. The OTC monograph process was set forth in 21 CFR part 330 (part 330). Prior to establishment of a final monograph, GRASE conditions for a therapeutic category were set forth in proposed rules as tentative final monographs. At the time of the passage of the CARES Act, certain OTC monographs were still at the proposed rulemaking stage, either in whole or in part.

In the course of the OTC drug review, FDA also determined when there was not sufficient evidence to demonstrate certain conditions (*e.g.,* active ingredients for specific uses) were GRASE. In such cases, FDA often expressly codified these determinations that certain conditions were not GRASE (see, *e.g.,* § 310.545 (21 CFR 310.545)). In addition, part 201, subpart G (21 CFR part 201, subpart G), includes specific labeling requirements for certain drugs, including OTC monograph drugs (see, *e.g.,* § 201.326, requiring warnings and other labeling for OTC drug products containing internal analgesic and antipyretic active ingredients).

B. Regulatory Framework for OTC Monograph Drugs Under the CARES Act

The CARES Act added section 505G to the FD&C Act, which revised the framework for the regulation of OTC

monograph drugs.[1] Under section 505G of the FD&C Act, the rulemaking process for establishing, revising, and amending OTC monographs was replaced with an administrative order process. In addition, among other things, section 505G of the FD&C Act provides a baseline status that, as of the date of enactment of the CARES Act, a drug that satisfies certain requirements described in section 505G(a)(1) or (2) is: (1) Deemed to be generally recognized as safe and effective under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1); (2) not a new drug under section 201(p) of the FD&C Act; and (3) not subject to section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)). To obtain this status, among other things, a drug either must be one that is in conformity with the requirements for nonprescription use of a final monograph issued under part 330 (except as provided in section 505G(a)(2) of the FD&C Act),[2] as well as other requirements; [3] or must be one that is: (1) Classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330 and (2) in conformity with the proposed requirements for nonprescription use of such tentative final monograph and any applicable subsequent determination by FDA, as well as other requirements.[4] Other applicable requirements in section 505G(a)(1) of the FD&C Act include conditions or requirements under section 505G(b), (c), and (k) of the FD&C Act.

Complementary to the requirements for conformity to tentative final or final monographs described in section 505G(a)(1) and (2) of the FD&C Act, Congress provided that, under section 505G(b)(8) of the FD&C Act, a final monograph or tentative final monograph that establishes conditions of use for a drug described in section 505G(a)(1) or (2) of the FD&C Act and that represents the most recently issued version of the conditions of use, including as modified, in whole or in part, by any proposed or final rule, is deemed to be a final order. These deemed final orders provide the current OTC drug monograph conditions that are in effect for each therapeutic category addressed by them. Final orders may be amended, revoked, or otherwise modified in accordance with the procedures of section 505G of the FD&C Act. Under section 505G(b)(8)(C) of the FD&C Act, the deemed establishment of a final order is construed to include technical amendments necessary to ensure that the final order is appropriately harmonized, in terms of terminology or cross-references, with the applicable provisions of the FD&C Act (and regulations) and any other final orders issued under section 505G.

Congress also deemed certain regulations, as in effect on the day before the date of the enactment of the CARES Act (*i.e.,* March 26, 2020), to be final orders under section 505G(b) of the FD&C Act. In particular, section 505G(k)(2)(A) of the FD&C Act deemed the provisions of § 310.545 to be a final order under section 505G(b). Also, section 505G(k)(2)(B) of the FD&C Act deemed regulations establishing requirements for specific nonprescription drugs marketed pursuant to section 505G (including such requirements in 21 CFR parts 201 and 250) to be final orders under section 505G(b), as they apply to drugs subject to section 505G(a)(1) through (4) or otherwise subject to an order under section 505G.

In addition, section 505G(k)(3) of the FD&C Act provides that regulations establishing final monographs and the procedures governing the OTC drug review under part 330 and other relevant parts of title 21 of the CFR, shall be withdrawn or revised to make technical changes to ensure conformity with appropriate terminology and cross-references. Section 505G(k)(3) of the FD&C Act also provides that any such withdrawal or technical changes shall be made without public notice and comment and shall be effective upon publication through notice in the **Federal Register** (or upon such date as specified in such notice).

II. Procedures for Posting Final Orders as Deemed by Section 505G of the FD&C Act

The final orders as deemed by section 505G of the FD&C Act were made effective upon enactment of the CARES Act on March 27, 2020. By this notice, FDA is announcing the availability on its website of certain deemed final orders and providing the public information on the process for making available deemed final orders, including details on how the public can access and view the final orders. FDA is posting these final orders to provide the public a convenient resource to view OTC monographs and non-monograph conditions. The process for FDA issuing proposed, final, and interim final orders under section 505G(b) of the FD&C Act to add, modify, or remove OTC monograph conditions is generally described in section 505G(b) and is not addressed in this Notice. Additional information, including questions and answers on this process, can be found on FDA's OTC monograph web page at *https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act,* and further information will be provided when FDA issues its first proposed order.

A. Process for Making Available Final Orders as Deemed by Section 505G(b)(8) of the FD&C Act

FDA is announcing its process for making available final orders as deemed by section 505G(b)(8) of the FD&C Act. FDA reviewed all final monographs published in the CFR, beginning with 21 CFR part 331, and the rulemaking histories for each OTC monograph therapeutic category, to identify all relevant final monographs and tentative final monographs that established conditions of use for a drug described in section 505G(a)(1) of the FD&C Act and that represented the most recently issued version of the conditions of use, including as modified, in whole or in part, by any proposed or final rule. As noted above, the relevant requirements for sunscreen drugs subject to section 505G of the FD&C Act, in terms of conformity with a final monograph for purposes of section 505G(a)(1)(A)(i), were set forth in section 505G(a)(2) and consist of the requirements specified in 21 CFR part 352, as published on May 21, 1999, except that the applicable requirements governing effectiveness and labeling are those specified in § 201.327. Altogether, as indicated in table 1 below, FDA identified 32 final orders created by section 505G(b)(8) of the FD&C Act.

As further discussed below, FDA also identified certain regulations that established requirements for specific nonprescription drugs marketed pursuant to section 505G of the FD&C Act and, therefore, were deemed final orders by section 505G(k)(2)(B), only as they apply to drugs subject to section 505G(a)(1) through (4) or otherwise subject to an order under section 505G (*e.g.,* § 201.326, which set forth certain labeling requirements regarding warnings for OTC drug products containing internal analgesic and antipyretic active ingredients). To the extent regulations that were deemed to be final orders by section 505G(k)(2)(B) of the FD&C Act apply to OTC drugs addressed by a final order embodying an

[1] OTC drugs that are governed by the provisions of section 505G of the FD&C Act are referred to as OTC monograph drugs.

[2] Section 505G(a)(2) of the FD&C Act provides specific requirements for sunscreen drugs in terms of conformity with a final monograph, for purposes of section 505G(a)(1)(A)(i) of the FD&C Act.

[3] Section 505G(a)(1)(A) of the FD&C Act.

[4] Section 505G(a)(1)(B) of the FD&C Act.

OTC monograph, as deemed by section 505G(b)(8) of the FD&C Act, the relevant provisions may be incorporated into the final order(s) embodying the OTC monograph(s).

FDA assigned OTC monograph numbers to the resulting deemed final orders (see table 1). Table 1 provides the corresponding OTC monograph number and title for each of these OTC monographs and identifies the CFR citation, if applicable. Additionally, an order ID will be assigned in sequential order upon posting of all orders, including the deemed final orders.

Each OTC monograph embodied by a deemed final order is accompanied by a summary and a background section. In the background section, FDA describes the relevant proposed and final rules that constitute the deemed final order. Additionally, pursuant to section 505G(b)(8)(C) of the FD&C Act, OTC monographs embodied by deemed final orders include any technical amendments that are determined to be necessary to ensure that they are appropriately harmonized, in terms of terminology and cross-references, with applicable provisions of the FD&C Act, FDA regulations, and any other orders issued under section 505G. The background section generally describes any differences between the deemed final order and the proposed and final rules that constitute the order.

Some OTC monographs incorporate by reference specified material, published by an entity other than the United States government (*e.g.,* an ISO standard). This incorporated material is available for inspection at FDA. For further information about inspecting incorporated materials, see *https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act.* Copies of incorporated material may also be available from its publisher.

TABLE 1—OTC MONOGRAPHS AS REPRESENTED BY FINAL ORDERS DEEMED BY SECTION 505G(B)(8) OF THE FD&C ACT

OTC monograph number	CFR citation in title 21	OTC monograph title
M001	Part 331	Antacid Products for OTC Human Use.
M002	Part 332	Antiflatulent Products for OTC Human Use.
M003	N/A [1]	First Aid Antiseptic Drug products for OTC Human Use.
M004	Part 333, subpart B	First Aid Antibiotic Drug Products for OTC Human Use.
M005	Part 333, subpart C	Topical Antifungal Drug Products for OTC Human Use.
M006	Part 333, subpart D	Topical Acne Drug Products for OTC Human Use.
M007	N/A[1]	Laxative Drug Products for OTC Human Use.
M008	Part 335	Antidiarrheal Drug Products for OTC Human Use.
M009	Part 336	Antiemetic Drug Products for OTC Human Use.
M010	Part 338	Nighttime Sleep Aid Drug Products for OTC Human Use.
M011	Part 340	Stimulant Drug Products for OTC Human Use.
M012	Part 341	Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use.
M013	Part 343	Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for OTC Human Use.
M014	Part 344	Topical Otic Drug Products for OTC Human Use.
M015	Part 346	Anorectal Drug Product for OTC Human Use.
M016	Part 347	Skin Protectant Drug Products for OTC Human Use.
M017	Part 348	External Analgesic Drug Product for OTC Human Use.
M018	Part 349	Ophthalmic Drug Products for OTC Human Use.
M019	Part 350	Antiperspirant Drug Products for OTC Human Use.
M020	Part 352	Sunscreen Drug Products for OTC Human Use.
M021	Part 355	Anticaries Drug Products for OTC Human Use.
M022	N/A [1]	Oral Health Care Drug Products for OTC Human Use.
M023	N/A [1]	Poison Treatment Drug Products for OTC Human Use.
M024	Part 357, subpart B	Anthelminic Drug Products for OTC Human Use.
M025	Part 357, subpart C	Cholecystokinetic Drug Products for OTC Human Use.
M026	Part 357, subpart I	Deodorant Drug Products for Internal Use for OTC Human Use.
M027	N/A [1]	Orally Administered Menstrual Drug Products for OTC Human Use.
M028	Part 358, subpart B	Wart Remover Drug Products for OTC Human Use.
M029	Part 358, subpart D	Ingrown Toenail Relief Drug Products for OTC Human Use.
M030	Part 358, subpart F	Corn and Callus Remover Drug Products for OTC Human Use.
M031	Part 358, subpart G	Pediculicide Drug Products for OTC Human Use.
M032	Part 358, subpart H	Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis for OTC Human Use.

[1] Not applicable as there is no relevant CFR citation (*i.e.,* there were no final monographs at the time of enactment of the CARES Act).

B. Process for Making Available Final Orders as Deemed by Section 505G(k)(2) of the FD&C Act

Under section 505G(k)(2)(A) of the FD&C Act, the non-monograph conditions in § 310.545 in effect on the day before the date of enactment of the CARES Act (*i.e.,* March 26, 2020) were deemed to be a final order under section 505G(b). The provisions of § 310.545 list active ingredients for which there is not sufficient data to establish general recognition of the safety and effectiveness for the specified use in OTC drug products. Before posting the deemed final order containing these provisions, FDA intends to remove the compliance dates found in the regulation because the dates are no longer relevant, since any current product would have been introduced or delivered for introduction into interstate commerce well after the compliance date. FDA also intends to rearrange the listed active ingredients within each provision regarding a particular therapeutic category so that they generally appear in alphabetical order. When posting this final order, FDA will assign a final order ID and OTC non-monograph conditions number.

In addition, under section 505G(k)(2)(B) of the FD&C Act, regulations in effect on March 26, 2020, establishing requirements for specific

nonprescription drugs marketed pursuant to section 505G of the FD&C Act were deemed final orders under section 505G(b), only as they apply to drugs subject to section 505G(a)(1) through (4) of the FD&C Act or otherwise subject to a final order under section 505G. As discussed above, provisions from a regulation that was deemed to be a final order by section 505G(k)(2)(B) of the FD&C Act may be incorporated into a relevant final order embodying an OTC monograph under section 505G(b)(8). A deemed final order under section 505G(k)(2)(B) of the FD&C Act may also be posted as a separate, standalone final order. In the latter case, FDA intends to issue an accompanying notice in the **Federal Register** announcing its availability on our website. Regulations deemed to be final orders by section 505G(k)(2)(B) of the FD&C Act will remain in the CFR to the extent they also apply to drugs that are not subject to section 505G(a)(1) through (4) or otherwise subject to an order under section 505G.

C. Availability of Final Orders Including Those Deemed by Section 505G of the FD&C Act

FDA has established a new IT system with a web portal, *OTC Monographs@FDA*, which can be accessed through FDA's website. The portal will provide access to a repository of final orders under section 505G of the FD&C Act and is available at *https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm.* To access the final orders, go to the *OTC Monographs@FDA* portal at *https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm.* Under the ''Administrative Orders'' banner, click on the desired link under the ''Order ID'' heading and follow the prompts.

For ease of reference, FDA also is posting in the *OTC Monographs@FDA* portal the individual OTC monographs embodied by final orders under section 505G(b) of the FD&C Act, without any sections that accompany the monograph, such as the background section. To access just the OTC monographs, under the ''OTC Monographs'' banner, click on the desired link under the ''OTC Monograph ID'' heading and follow the prompts.

FDA will make available deemed final orders embodying OTC monographs in batches on a rolling basis until all 32 such orders, discussed above in section II.A (see also table 1), are available in the repository. FDA will also make available in the repository the final order that reflects the provisions of § 310.545, as deemed by section 505G(k)(2)(A) of the FD&C Act, and final orders regarding requirements for specific nonprescription drugs, as deemed by section 505G(k)(2)(B).

FDA is announcing that the *OTC Monographs@FDA* portal currently includes an initial batch of four deemed final orders embodying OTC monographs (see table 2). The posting of the remainder of these 32 deemed final orders, as well as the deemed final order under section 505G(k)(2)(A) of the FD&C Act, will not be announced in the **Federal Register** but will be announced on FDA's OTC monograph web page, *https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act.* FDA plans to issue a notice of availability in the **Federal Register** when posting in the repository final orders deemed by section 505G(k)(2)(B) of the FD&C Act.

TABLE 2—INITIAL BATCH OF POSTED FINAL ORDERS DEEMED BY SECTION 505G OF THE FD&C ACT

Order ID	OTC monograph number	CFR citation in Title 21	OTC monograph title
OTC000001	M002	Part 332	Antiflatulent Products for OTC Human Use.
OTC000002	M010	Part 338	Nighttime Sleep-Aid Drug Products for OTC Human Use.
OTC000003	M014	Part 344	Topical Otic Drug Products for OTC Human Use.
OTC000004	M030	Part 358, Subpart F.	Corn and Callus Remover Drug Products for OTC Human Use.

FDA encourages the public to frequently view our website at *https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act* and the *OTC Monographs@FDA* portal for the most up-to-date information about the status of posted final orders as deemed by section 505G of the FD&C Act. Questions regarding these final orders can be submitted to FDA at *druginfo@fda.hhs.gov.*

In the future, the repository will also include proposed orders, final orders, and interim final orders to add, amend, or remove OTC monograph conditions that are issued by FDA either on its own initiative or pursuant to an OTC monograph order request under section 505G(b)(5) of the FD&C Act. Information on the process for FDA issuing proposed, final, and interim final orders is provided in section 505G(b) of the FD&C Act. Additional information, including questions and answers on this process, can be found on FDA's OTC monograph web page (*https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act*), which will continue to be updated as FDA issues new orders.

III. Procedures for Withdrawing Regulations for Final Monographs and the Procedures Governing the OTC Drug Review, and Withdrawing and Making Technical Changes to Regulations in Part 330 and Other Relevant Parts of Title 21 of the CFR

Under section 505G(k)(3) of the FD&C Act, regulations establishing final monographs and the procedures governing the OTC drug review under part 330 and other relevant parts of title 21 of the CFR (as in effect on March 26, 2020) shall be withdrawn or revised to make technical changes to ensure conformity with appropriate terminology and cross-references. Section 505G(k)(3) of the FD&C Act also provides that any such withdrawal or technical changes shall be made without public notice and comment and shall be effective upon publication through notice in the **Federal Register** (or upon such date as specified in such notice).

FDA intends to issue a notice to withdraw the regulations establishing final monographs in title 21 of the CFR at a later date once all the relevant deemed final orders have been posted on FDA's *OTC monographs@FDA* web portal (*i.e.,* 21 CFR parts 331, 332, 333, 335, 336, 338, 340, 341, 343, 344, 346, 347, 348, 349, 350, 352, 355, 357, and 358). Prior to the withdrawal of such regulations, the public should reference the OTC monographs posted in the *OTC*

Monographs@FDA portal at *https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm,* to the extent the corresponding deemed final order has been added to the portal. Additionally, in either the same notice or a separate notice in the **Federal Register**, pursuant to section 505G(k)(3) of the FD&C Act, FDA intends to withdraw certain portions of the regulations governing the OTC drug review, and to make certain technical changes.

IV. Paperwork Reduction Act of 1995

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (Chapter 35 of title 44, United States Code) does not apply to collections of information made under section 505G of the FD&C Act. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required for collections of information, if any, in orders deemed to be final orders by section 505G of the FD&C Act.

Dated: September 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20393 Filed 9–20–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0281]

Agency Father Generic Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, Health and Human Service, HHS.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before October 21, 2021.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When requesting information, please include the document identifier 0990–0281–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Prevention Communication Formative Research.

Type of Collection: Extension.

OMB No.: 0990–0281—Office of Disease Prevention and Health Promotion.

Abstract: The Office of Disease Prevention and Health Promotion (ODPHP) is focused on developing and disseminating health information to the public. ODPHP faces an increasingly urgent interest in finding effective ways to communicate health information to America's diverse population. ODPHP strives to be responsive to the needs of America's diverse audiences while simultaneously serving all Americans across a range of channels, from print to new communication technologies. To carry out prevention information efforts, ODPHP is committed to conducting formative and usability research to provide guidance on the development and implementation of their communication and education efforts. The information collected will be used to improve communication, products, and services that support key office activities including: Healthy People, Dietary Guidelines for Americans, Physical Activity Guidelines for Americans, MyHealthfinder, the Move Your Way® Campaign, the President's Council on Sports, Fitness & Nutrition, health literacy and healthy aging. ODPHP communicates through its websites (*www.health.gov*) and through other channels including social media, print materials, interactive training modules, and reports. This request builds on previous formative research approaches to place more emphasis on Web-based data collection to allow greater geographical diversity among respondents, to decrease respondent burden, and to save government costs. Data collection will be qualitative and quantitative and may include in-depth interviews, focus groups, web-based surveys, omnibus surveys, card sorting, and various forms of usability testing of materials and interactive tools to assess the public's understanding of disease prevention and health promotion content, responses to prototype materials, and barriers to effective use. The program is requesting a 3-year clearance. The type of respondents are consumers and health professionals which will be surveyed on an annual basis.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Consumers (screening & omnibus survey)	7725	1	10/60	1287.5
Consumers (qualitative testing)	1250	1	1	1250
Consumers (focus groups)	575	1	1.5	862.5
Consumers (screening & intercepts)	35250	1	5/60	2937.5
Consumers (survey)	10000	1	15/60	2500
Consumers (gatekeeper reviews)	325	1	30/60	162.5
Consumers (cognitive tests)	50	1	2	100
Health care professionals (screening)	1350	1	10/60	225
Health care professionals (interview)	50	1	1	50
Health care professionals (focus group)	400	1	1.5	600
Total	.....	.....	.....	9,975