Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Richard Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 51, Rm. 4132, Silver Spring, MD 20993, 301–796–1697.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances.'' This guidance finalizes the draft guidance for industry entitled ''Dissolution Testing and Specification Criteria for Immediate-Release Solid Oral Dosage Forms Containing Biopharmaceutics Classification System Class 1 and 3 Drugs'' (August 2015) (FR 80 46019), and the recommendations in this guidance clarify the recommendations in the guidance for industry entitled ''Dissolution Testing of Immediate Release Solid Oral Dosage Forms'' (August 1997) (FR 62 44974) for high solubility drug substances in IR drug products that meet the conditions described in section III of this guidance. For drug substances that do not meet the conditions in this guidance, sponsors/applicants should follow the recommendations provided in the August 1997 guidance.

The title of this guidance has been revised to better reflect its focus on the solubility of the drug substance in the drug product. Therefore, a direct reference to biopharmaceutics classification system class 1 and class 3 is not necessary because permeability requirements are not within the focus of this guidance.

Drug absorption from a solid dosage form after oral administration depends on the release of the drug substance from the drug product, the dissolution or solubilization of the drug under physiological conditions, and the permeation across the gastrointestinal membrane. NDAs and ANDAs submitted to FDA contain bioavailability (BA) or bioequivalence (BE) data and in vitro dissolution data that, together with chemistry, manufacturing, and controls data, characterize the quality and performance of the drug product. In vitro dissolution data are generally obtained from: (1) Batches used in pivotal clinical and/or BA/BE studies, (2) batches used as stability registration batches, and (3) batches used in other human studies conducted during product development. In general, knowledge about the solubility, permeability, dissolution, and pharmacokinetics of a drug product is considered when defining dissolution acceptance criteria for the drug approval process.

Immediate-release solid oral dosage form drug products containing high solubility drug substances are considered to be relatively low risk regarding the impact of dissolution on in vivo performance, provided the in vitro performance meets or exceeds the recommendations discussed within this guidance. This guidance establishes standard dissolution methodology and acceptance criteria that are appropriate for highly soluble drug substances that are formulated in IR dosage form. The availability of these standards will facilitate the rapid development of dissolution methodology and related acceptance criteria with no requirement to show discriminatory ability of the dissolution method for these products during drug product development. In addition, these standards will facilitate FDA's evaluation of the data submitted in the application.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17025 Filed 8–8–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0180]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

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: Fax written comments on the collection of information by September 10, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0810. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@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.

Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications; OMB Control Number 0910–0810—Extension

In order to conduct educational and public information programs relating to tobacco use as authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA's Center for Tobacco Products will create and use a variety of media to inform and educate the public, tobacco retailers, and health professionals about the risks of tobacco use, how to quit using tobacco products, and FDA's role in regulating tobacco.

To ensure that these health communication messages have the highest potential to be received, understood, and accepted by those for whom they are intended, the Center for Tobacco Products will conduct research and studies relating to the control and prevention of disease. In conducting such research, FDA will employ formative pretests. Formative pretests are conducted on a small scale, and their focus is on developing and assessing the likely effectiveness of communications with specific target audiences. This type of research involves: (1) Assessing audience knowledge, attitudes, behaviors, and other characteristics for the purpose of determining the need for and developing health messages, communication strategies, and public information programs and (2) pretesting these health messages, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions.

Formative pretesting is a staple of best practices in communications research. Obtaining voluntary feedback from intended audiences during the development of messages and materials is crucial for the success of every communication program. The purpose of obtaining information from formative pretesting is that it allows FDA to improve materials and strategies while revisions are still affordable and possible. Formative pretesting can also avoid potentially expensive and dangerous unintended outcomes caused by audiences' interpreting messages in a way that was not intended by the drafters. By maximizing the effectiveness of messages and strategies for reaching targeted audiences, the frequency with which tobacco communication messages need to be modified should be greatly reduced.

The voluntary information collected will serve the primary purpose of providing FDA information about the perceived effectiveness of messages, advertisements, and materials in reaching and successfully communicating with their intended audiences. Quantitative testing messages and other materials with a sample of the target audience will allow FDA to refine messages, advertisements, and materials, including questionnaires or images, directed at consumers while the materials are still in the developmental stage.

In the **Federal Register** of February 13, 2018 (83 FR 6190), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA-related comment was received.

Comment: The comment recommends that FDA should research and develop communications about educating adults about the continuum of risk, and educating adults to not provide tobacco products to youth.

Response: FDA appreciates the comment. The content and focus on studies submitted through this generic clearance will depend on Agency priorities and needs, and is not yet determined at this time.

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
Screener	130,500	1	130,500	0.083 (5 minutes)	10,831
Self-Administered Surveys	27,000	1	27,000	0.33 (20 minutes)	8,910
Total					19,741

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

The number of respondents to be included in each new survey will vary, depending on the nature of the material or message being tested and the target audience. The burden for this information collection extension is proposed to increase by 12,613 hours since the last OMB approval. The burden increase is due to an increase in the number of respondents and the categories of respondents.

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17044 Filed 8–8–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2495]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants

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 the information collection associated with the guidance to assist manufacturers who wish to voluntarily label their foods (human and animal) as being made with or without bioengineering, or the use of bioengineered ingredients, to ensure that labeling is truthful and not misleading.