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.'' We will review this copy, including the claimed confidential information, in our 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: Mabel Lee, Center Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 28, 2018 (83 FR 49103), FDA published a notice with a 60-day comment period inviting interested parties to provide information on specific topics related to the labeling of plant-based products with names that include the names of dairy foods such as ''milk,'' ''cultured milk,'' ''yogurt,'' and ''cheese.'' The information will inform our development of an approach to the labeling of plant-based products that consumers may substitute for dairy foods. We asked that comments be submitted by November 27, 2018.

We have received requests for a 120-day extension of the comment period for the notice. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful responses to the questions that appeared in the notice requesting data and other evidence in support of answers.

We have considered the requests and are extending the comment period for another 60 days, until January 28, 2019. We believe that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying any potential further action on these important issues.

Dated: November 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25347 Filed 11–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0500]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions; Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

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 December 21, 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 0910–0572. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

OMB Control Number 0910–0572—Extension

FDA's regulations governing the content and format of labeling for human prescription drug and biological products were revised in the **Federal Register** of January 24, 2006 (71 FR 3922) (the 2006 labeling rule) to require that the labeling of new and recently approved products contain highlights of prescribing information, a table of contents for prescribing information, reordering of certain sections, minor content changes, and minimum graphical requirements. These revisions were intended to make it easier for health care practitioners to access, read, and use information in prescription drug labeling; to enhance the safe and effective use of prescription drug products; and to reduce the number of adverse reactions resulting from medication errors because of misunderstood or incorrectly applied drug information.

Currently, § 201.56 (21 CFR 201.56) requires that prescription drug labeling contain certain information in the format specified in either § 201.57 (21 CFR 201.57) or § 201.80 (21 CFR 201.80), depending on when the drug was approved for marketing. Section 201.56(a) sets forth general labeling requirements applicable to all prescription drugs. Section 201.56(b) specifies the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in §§ 201.56(d) and 201.57. Section 201.56(c) sets forth the schedule for implementing these revised content and format requirements. Section 201.56(e) specifies the sections and subsections, required and optional, for the labeling of older prescription drugs not subject to the revised format and content requirements.

Section 201.57(a) requires that prescription drug labeling for new and more recently approved prescription drug products include a ''Highlights of Prescribing Information'' section. The ''Highlights'' section provides a concise extract of the most important information required under § 201.57(c) (the Full Prescribing Information (FPI)), as well as certain additional information important to prescribers. Section 201.57(b) requires a table of contents to

prescribing information entitled ''Full Prescribing Information: Contents,'' consisting of a list of each heading and subheading along with its identifying number to facilitate health care practitioners' use of labeling information. Section 201.57(c) specifies the contents of the FPI. Section 201.57(d) mandates the minimum specifications for the format of prescription drug labeling and establishes minimum requirements for key graphic elements such as bold type, bullet points, type size, and spacing.

Older drugs not subject to the revised labeling content and format requirements in § 201.57 are subject to labeling requirements at § 201.80. Section 201.80(f)(2) requires that, within 1 year, any FDA-approved patient labeling be referenced in the ''Precautions'' section of the labeling of older products and either accompany or be reprinted immediately following the labeling.

Annual Burden for Prescription Drug Labeling Design, Testing, and Submitting to FDA for New Drug Applications (NDAs) and Biologics License Applications (BLAs) (§§ 201.56 and 201.57)

New drug product applicants must: (1) Design and create prescription drug labeling containing ''Highlights,'' ''Contents,'' and FPI; (2) test the designed labeling (*e.g.,* to ensure that the designed labeling fits into carton-enclosed products); and (3) submit it to FDA for approval. Based on the projected data used in the January 24, 2006, final rule, FDA estimates that it will take applicants approximately 2,327 hours to design, test, and submit prescription drug labeling to FDA as part of a NDA or a BLA under the revised regulations. Currently, approximately 406 applicants submit approximately 541 new applications (NDAs and BLAs) to FDA annually, totaling 1,258,907 hours.

In the **Federal Register** of July 20, 2018 (83 FR 34596), we published a 60-day notice requesting public comment on the proposed collection of information. We received two comments. One comment encouraged the use of ''provider-neutral language'' in specific regulations. The second comment discussed the distribution of package inserts for prescription drugs via paper labeling. Because these comments do not apply to the regulations associated with the information collection, we have not addressed them here.

Our estimate of the burden for the information collection is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part and activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response	Total hours
Labeling Requirements in §§ 201.56 and 201.57	406	1.332	541	2,327	1,258,907

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Estimates may not sum due to rounding.

Our estimated burden for the information collection reflects an overall increase of 602,503 hours and a corresponding increase of 345 records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: November 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25352 Filed 11–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal of the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services is hereby giving notice that the charter for the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) has been renewed.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Designated Federal Officer for the ACBTSA, Senior Advisor for Blood and Tissue Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L100, Washington, DC 20024. Phone: (202) 795–7697; Fax: (202) 691–2102; Email: *ACBTSA@hhs.gov*.

SUPPLEMENTARY INFORMATION: ACBTSA is a non-discretionary Federal advisory committee. ACBTSA is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service (PHS) Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees.

The ACBTSA advises, assists, consults with, and makes policy recommendations to the Secretary, through the Assistant Secretary for Health, regarding these broad responsibilities related to the safety of blood, blood products, tissues, and organs. For solid organs and blood stem cells, the Committee's work is limited to policy issues related to donor derived infectious disease complications of transplantation.

To carry out its mission, the ACBTSA provides advice to the Secretary through the Assistant Secretary for Health on a range of policy issues to include: (1) Identification of public health issues through surveillance of blood and tissue safety issues with national biovigilance data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical, and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (*e.g.,* product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues.

On September 25, 2018, the Secretary approved for the ACBTSA charter to be renewed. The new charter was effected and filed with the appropriate Congressional committees and the Library of Congress on October 9, 2018. Renewal of the Committee's charter gives authorization for the Committee to continue to operate until October 9, 2020.