

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard <sup>1</sup>	Reference No. and Date
<b>O. Physical Medicine</b>		
16–202 .....	RESNA Standard for Wheelchairs Volume 4: Wheelchairs and Transportation .....	RESNA WC–4:2017.
<b>P. Radiology</b>		
	No new entries at this time	
<b>Q. Software/Informatics</b>		
13–104 .....	Software Cybersecurity for Network-Connectable Products, Part 2–1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems.	ANSI/UL 2900–2–1, First Edition September 1, 2017.
<b>R. Sterility</b>		
	No new entries at this time	
<b>S. Tissue Engineering</b>		
15–53 .....	Standard Guide for Assessing Medical Device Cytocompatibility with Delivered Cellular Therapies.	ASTM F3206 –17.
15–54 .....	Standard Guide for in vivo Evaluation of Rabbit Lumbar Intertransverse Process Spinal Fusion Model.	ASTM F3207–17.

<sup>1</sup> All standard titles in this table conform to the style requirements of the respective organizations.

#### IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. FDA will be incorporating the modifications and revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will be announcing additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary. Beginning with recognition list 049, FDA will no longer include in the database the CDRH Office and Division associated with recognized standards, Devices Affected, and Processes Affected. Beginning with recognition list 049 FDA will automatically incorporate, upon publication, a U.S. parallel adoption of an existing recognized international standard.

#### V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to [CDRHStandardsStaff@fda.hhs.gov](mailto:CDRHStandardsStaff@fda.hhs.gov). To be considered, such recommendations should contain, at a minimum, the following information available at <https://www.fda.gov/MedicalDevices/>

*Device Regulation and Guidance/Standards/ucm123739.htm*.

Dated: May 31, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA–2018–D–1635]

#### Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President's Emergency Plan for AIDS Relief; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President's Emergency Plan for AIDS Relief.” This draft guidance describes circumstances under which an applicant may be eligible for a barrier-to-innovation waiver for some new drug applications (NDAs) for fixed-combination versions and single-entity versions of previously approved antiretroviral therapies for the

treatment of human immunodeficiency virus (HIV).

**DATES:** Submit either electronic or written comments on the guidance August 6, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

##### *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-2018-D-1635 for “Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President’s Emergency Plan for AIDS Relief.” Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug 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 draft guidance document. **FOR FURTHER INFORMATION CONTACT:** Ted Palat, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Rm. 2185, Silver Spring, MD 20993, 240-402-8739, [Ted.Palat@fda.hhs.gov](mailto:Ted.Palat@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President’s Emergency Plan for AIDS Relief.” The draft guidance describes the circumstances under which certain applications for fixed-combination and single-entity versions of previously approved antiretroviral therapies for the treatment of HIV under the President’s Emergency Plan for AIDS Relief (PEPFAR) may be eligible for a barrier-to-innovation waiver.

In October 2006, to encourage applicants to submit applications for HIV combination therapies that can be used in PEPFAR, FDA issued a final guidance entitled “Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV” (fixed-combination guidance). Attachments to the fixed-combination guidance describe some scenarios for approval of fixed-combination for the treatment of HIV and provide examples of drug combinations considered acceptable as fixed combinations and examples of those not considered acceptable as fixed

combinations. Although the 2006 fixed-combination guidance focuses on fixed combinations, the scientific principles outlined in the guidance also apply to single ingredient versions of antiretroviral drugs that are components of regimens listed in Attachment B. The guidance also explains that the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides for certain circumstances in which FDA may grant a waiver or reduction in user fees.

This draft guidance is a revision of the guidance for industry entitled “User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR,” issued February 2007. In this guidance, FDA provides information about the circumstances under which certain applications for fixed-combination and single-entity versions of previously approved antiretroviral therapies for the treatment of HIV under PEPFAR may be eligible for a barrier-to-innovation waiver.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President’s Emergency Plan for AIDS Relief.” 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 draft guidance contains information collection provisions 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 burden of information collection associated with requesting waivers of user fees (including PEPFAR waivers) was previously approved under OMB control number 0910-0693. The burden for completing and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) is not included in this analysis as the burden is already approved under OMB control number 0910-0297. The collections of information associated with submission of a new drug application or biologics license application are approved under OMB control numbers 0910-0001 and 0910-0338, respectively.

##### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/>

*GuidanceComplianceRegulatory Information/Guidances/default.htm* or <https://www.regulations.gov>.

Dated: June 1, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0781]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim**

**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 (PRA).

**DATES:** Fax written comments on the collection of information by July 9, 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 [aira\\_submission@omb.eop.gov](mailto:aira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0428. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JennaLynn 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](mailto: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.

**Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim—21 CFR 101.82**

*OMB Control Number 0910-0428—Extension*

Section 403(r)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)(A)) provides for the use of food label statements characterizing a relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health-related condition only where that statement meets the requirements of the

regulations issued by the Secretary of Health and Human Services to authorize the use of such a health claim. Section 101.82 (21 CFR 101.82) of our regulations authorizes a health claim for food labels about soy protein and the risk of coronary heart disease. Accordingly, FDA established the previously referenced information collection in support of the regulation. In the **Federal Register** of October 31, 2017 (82 FR 50324), we published a proposed rule to revoke the underlying regulation found at § 101.82. We are taking this action based on our review of the totality of publicly available scientific evidence currently available and our tentative conclusion that such evidence does not support our previous determination that there is significant scientific agreement among qualified experts for a health claim regarding the relationship between soy protein and reduced risk of coronary heart disease. Upon finalization of the proposed rule, the associated information collection requirements under this OMB control number will be revoked. Until such time and in accordance with the PRA, we retain our currently approved burden estimate for the information collection displayed in table 1 of this notice.

In the **Federal Register** of March 8, 2018 (83 FR 9856), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
101.82(c)(2)(ii)(B) .....	25	1	25	1	25

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

Based on our current experience with the use of health claims, we estimate 25 firms market products bearing a soy protein/coronary heart disease health claim and that perhaps one of each firm's products might contain non-soy sources of protein along with soy protein. The records currently required to be retained under § 101.82(c)(2)(ii)(B) are the records, *e.g.*, the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is limited to assembling and retaining the records, which we estimate will take 1 hour annually.

Dated: May 30, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-12216 Filed 6-6-18; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-N-0961]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public