ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total/annual burden (in hours)
Coordination Activities (Coordinator)	6	1	3	18
Prep Email Request (Director)	9	1	.5	5
Preparatory Interview (Director, Onsite coordinator)	18	1	1	18
Full Interview for Head Start Staff Protocol	70	1	1.5	105
Full Interview for Non-Head Start Staff Protocol	12	1	1.5	18

Estimated Total Annual Burden Hours: 164 hours.

Authority: Head Start Act section 640 [42 U.S.C. 9835].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–12967 Filed 6–15–22; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0745]

Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

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of a draft document entitled ''Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies; Draft Guidance for Industry.'' The draft guidance describes a standards recognition program for regenerative medicine therapies (SRP–RMT) at FDA's Center for Biologics Evaluation and Research (CBER) designed to identify Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products regulated by CBER when such standards are appropriate. The voluntary use of recognized VCS can assist stakeholders in more efficiently meeting regulatory requirements and increasing regulatory predictability for RMT products. The program is modeled after the formal standards and conformity assessment program (S–CAP) for medical devices.

DATES: Submit either electronic or written comments on the draft guidance by September 14, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments on the collection of information by August 15, 2022.

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–2022–D–0745 for ''Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies; Draft Guidance for Industry.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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 Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the draft guidance: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the proposed collection of information: 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:

I. Background

FDA is announcing the availability of a draft document entitled ''Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies; Draft Guidance for Industry.'' The draft guidance describes a program at FDA's CBER for recognition of VCS relevant to RMT products regulated in CBER. The SRP–RMT is designed to identify and recognize VCS to facilitate the development and assessment of RMT products. The voluntary use of recognized VCS can assist stakeholders in more efficiently meeting regulatory requirements and increasing regulatory predictability for RMT products. The program parallels the S–CAP for medical devices. CBER is issuing this draft guidance to obtain public comments on the program.

The draft guidance describes the purpose of the program, how the SRP–RMT is expected to facilitate RMT development, and describes how the Office of Tissues and Advanced Therapies in CBER generally intends to evaluate VCS for recognition in the SRP–RMT. This program will not apply to: (1) statutory and regulatory standards that are legally binding, such as certain provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*); (2) standards developed by Standards Development Organizations (SDOs) that do not follow consensus mechanisms; or (3) electronic data exchange standards for submissions to CBER.

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 ''Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies.'' 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.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3521), 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 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.

Request for Recognition of a Voluntary Consensus Standard

OMB Control Number 0910–0338—Revision

Description: The draft guidance for industry entitled ''Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies'' provides guidance to industry about a program at CBER for recognition of VCS relevant to RMT products regulated in CBER. The voluntary use of recognized standards can assist stakeholders in more efficiently meeting regulatory requirements and increasing regulatory predictability for RMT products.

The draft guidance describes the procedures CBER follows when a request for recognition of a VCS is received. The draft guidance also provides that any interested party may request recognition of a VCS. Section V of the draft guidance provides that a stakeholder can request recognition of a specific VCS by submitting an email request to SRP–RMT, and recommends that the request should, at a minimum, contain the following information:

- Name and electronic or mailing address of the requester;
- Name of the SDO;
- Title of the VCS;
- The VCS reference or SDO designation number and publication date (*e.g.,* Q1234–2019);
- Proposed list of products for which a standard could apply routinely;
- Rationale for request; and
- A brief description of the testing, performance, or other characteristics of the RMT products(s) or process(es) that would be addressed by the proposed standard.

We will use the requests to help identify for recognition appropriate VCS to facilitate the development and assessment of RMT products. The information is needed to support FDA's efforts to protect the public health and increase regulatory predictability for RMT products. We are requesting approval to revise the information collections included in OMB control number 0910–0338 to include the information collection associated with the draft guidance.

Description of Respondents: Respondents to this collection of information are product sponsors, applicants and other stakeholders interested in the development of RMT products regulated in CBER.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/draft guidance section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for recognition of a voluntary consensus standard/Section V	9	1	9	3	27

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

In preparing our estimates of the annual number of respondents and the average burden per response, we reviewed estimates made by other FDA Centers regarding similar requests for recognition of standards, specifically the Center for Devices and Radiological Health (83 FR 46740 at 46742; September 14, 2018) and the Center for Drug Evaluation and Research (84 FR 4076 at 4078; February 14, 2019). We note that standards development is a lengthy process and the list of VCS that are potentially suitable for recognition by CBER is growing but not extensive. We determined that it would be reasonable to use an estimate of nine respondents, consistent with the estimates made by the other Centers. However, we increased our estimate of the amount of time it would take to prepare a request from 1 hour to 3 hours, given the amount of information that needs to be included in each VCS request. Still, because this is a new program, FDA is uncertain of the burden and seeks input on this estimate.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12928 Filed 6–15–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–1154]

Determination That THEO–DUR (Theophylline) Extended-Release Tablets, 100 Milligrams and 300 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that THEO–DUR (theophylline) extended-release tablets, 100 milligrams (mg) and 300 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Nisha Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–4455, *Nisha.Shah@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

THEO–DUR (theophylline) extended-release tablets, 100 mg and 300 mg, are the subject of ANDA 085328, currently held by Merck & Co., Inc. (previously held by Schering Corporation),[1] initially approved on April 12, 1979. THEO–DUR is indicated for the treatment of the symptoms and reversible airflow obstruction associated with chronic asthma and other chronic lung diseases, *e.g.,* emphysema and chronic bronchitis.

In a letter dated March 18, 2003, Schering Corporation requested withdrawal of ANDA 085328 for THEO–DUR (theophylline) extended-release tablets. In the **Federal Register** of May 5, 2004 (69 FR 25124), FDA announced that it was withdrawing approval of ANDA 085328, effective June 4, 2004.

Lachman Consultants submitted a citizen petition dated October 25, 2021 (Docket No. FDA–2021–P–1154), under 21 CFR 10.30, requesting that the Agency determine whether THEO–DUR (theophylline) extended-release tablets, 300 mg, were withdrawn from sale for reasons of safety or effectiveness.

[1] In 2009, Schering Corporation merged with Merck and is now referred to as Merck & Co., Inc.