



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-0745]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biologics License Applications Procedures and Requirements; Voluntary Consensus Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0338. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@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.

Biologics License Applications (BLAs) Procedures and Requirements

OMB Control Number 0910-0338--Revision

This information collection helps support FDA implementation of statutory and regulatory requirements that govern biologics product licensing. We have issued regulations in 21 CFR parts 600-680 setting forth applicable standards and procedures that include associated reporting, recordkeeping, and disclosure requirements. Respondents to the information collection are persons or entities who engage in manufacture of biologics products. We provide information on our website at <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber> regarding BLAs, including available Agency resources.

We are revising the information collection to support implementation of a standards recognition program for regenerative medicine therapies at FDA's Center for Biologics Evaluation and Research (CBER) designed to identify and recognize 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 draft guidance for industry entitled "Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies" (June 2022) describes procedures CBER will follow when a request for recognition of a VCS is received. The draft guidance also explains that any interested party may request recognition of a VCS. The draft guidance document is available for download at <https://www.fda.gov/media/159237/download>. We issued the guidance document consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We intend on finalizing the guidance document upon OMB approval of the attendant information collection.

The use of recognized VCS can assist stakeholders in more efficiently meeting regulatory requirements and increasing regulatory predictability for RMT products. We will use requests for recognition to help identify appropriate VCS that facilitate the development and assessment

of RMT products. We encourage sponsors to use FDA-recognized VCS in submissions, as conformity to relevant standards helps streamline regulatory review, foster quality, and may facilitate a manufacturer’s preparation of submissions. As explained in Section V of the draft guidance document, any stakeholder can request recognition of a specific VCS.

In the *Federal Register* of June 16, 2022 (87 FR 36327), we published a 60-day notice announcing the availability of the draft guidance and invited public comment on the proposed collection of information. We received comment letters supportive of our use of voluntary consensus standards for regenerative medicine therapies. Comments encouraged broad application of a voluntary consensus program. No comments were received regarding the request for recognition information collection provisions and FDA’s need for the information; the accuracy of our burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected in the requests; or ways to minimize burden of the requests. Comments are being considered as the guidance is finalized.

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 Burden¹

Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies; Guidance for Industry	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Request for recognition of a voluntary consensus standard and submission of information as specified in Section V	9	1	9	3	27

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

Our estimate is based on our experience with similar information collection activities.

We note that standards development can be a lengthy process and provide an estimate we believe

reflects the amount of time necessary to prepare and submit the information as discussed in
Section V of the guidance document.

Dated: August 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-17460 Filed: 8/14/2023 8:45 am; Publication Date: 8/15/2023]