

Persons with access to the internet may obtain the draft guidance at <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>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2024-N-3902; FDA-2024-N-4754; FDA-2018-D-1873; FDA-2024-N-4146; FDA-2021-N-0862; FDA-2008-D-0053; FDA-2024-N-5338; FDA-2024-N-3112; FDA-2024-N-4167; FDA-2024-N-3675; FDA-2025-N-0338; FDA-2025-N-2193]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB Control No.	Date approval expires
Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	0910-0045	07/31/2028
Financial Disclosure by Clinical Investigators	0910-0396	07/31/2028
MDUFMA Small Business Qualification Certification	0910-0508	07/31/2028
Biosimilar User Fee Program	0910-0718	07/31/2028
General Drug Labeling Provisions and OTC Monograph Drug User Fee Submissions	0910-0340	07/31/2028
Applications for FDA Approval to Market a New Drug	0910-0001	07/31/2027
Prescription Drug Advertisements and Product Communications	0910-0686	07/31/2028
Medical Device Labeling Requirements	0910-0485	07/31/2028
Interstate Shellfish Dealer's Certificate	0910-0021	07/31/2028
Postmarketing Adverse Drug Experience Reporting	0910-0230	07/31/2028
Labeling Requirements for Human Prescription Drug and Biological Products	0910-0572	07/31/2028
Pharmaceutical Distribution Supply Chain	0910-0806	08/31/2028
Export Notification and Recordkeeping Requirements	0910-0482	09/30/2028
Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products	0910-0749	09/30/2028

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6159]

Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft document entitled “Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry.” The draft guidance document provides sponsors engaged in the development of regenerative medicine therapies for serious or life-threatening diseases or conditions with FDA’s recommendations on the expedited development and review of these therapies. This draft guidance, when finalized, will supersede the final guidance of the same title dated February 2019.

DATES: Submit either electronic or written comments on the draft guidance by November 24, 2025 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