program area, and the geographic areas served for the last complete FY.

The Supporting America's Children and Families Act, Public Law 118–258, was signed into law on January 4, 2025. This law reauthorizes and amends title IV–B programs. The new title IV–B reporting requirements will be added to the CFSP/APSR instructions. New requirements under title IV–B, subpart 3 requires that CB reduce administrative burden on the title IV–B program to eliminate duplication and streamline reporting requirements to reduce the number of hours required for compliance by at least 15 percent in coordination with activities required under the Paperwork Reduction Act. CB has already begun these activities to gather input to streamline reporting and reduce burden.

Respondents: Currently, states, territories, and tribes must complete the CFSP, APSR, and CFS–101. There are approximately 180 tribal entities that currently receive IV–B funding. There are 53 states (including the Commonwealth of Puerto Rico, the District of Columbia, and the Virgin Islands) that must complete the CFSP, APSR, and CFS–101.

Annual Burden Estimates: Burden estimates have been adjusted to reflect the updates to the APSR and the CFSP and the elimination of the caseworker visit data. The average burden per response for the APSR has been reduced from 82 hours to 50 hours and for the CFSP it has been reduced from 123 hours to 90 hours. Overall, this is a 48 percent reduction in burden associated with this information collection.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
APSR	233	3	50	34,950	11,650
CFSP	47	1	90	4,230	1,410
CFS–101, Part I, Part II, and III	233	3	5	3,495	1,165
Estimated Total Annual Burden Hours					14,225

Authority: Title IV–B, subparts 1, 2, and 3 of the Social Security Act (the Act), and title IV–E, section 477 of the Act; sections 106 and 108 of CAPTA (42 U.S.C. 5106a. and 5106d.); and Supporting America's Children and Families Act, Pub. L. 118–258, signed into law on January 4, 2025.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–14304 Filed 7–15–26; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7606]

Process for FDA Data Requests To Inform Certain Over-the-Counter Monograph Drug Activities; Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the process for FDA to issue Data Requests for the submission of data from the public to help inform certain future over-the counter (OTC) monograph drug activities, including development of FDA-initiated proposed orders to modify conditions described in an OTC monograph. FDA is issuing this notice to inform the public and interested parties of the process that FDA is implementing to issue these Data Requests.

DATES: The announcement of the process is published in the **Federal Register** on July 16, 2026.

FOR FURTHER INFORMATION CONTACT: Michael Boblitz, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–002, 301–837–7651.

SUPPLEMENTARY INFORMATION:

I. Background

Section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h) sets forth the framework for the regulation of OTC monograph drugs.[1] OTC monograph drugs may be marketed without a new drug application approved under section 505 of the FD&C Act (21 U.S.C. 355) if they meet the requirements of section 505G of the FD&C Act, as well as other applicable requirements. An OTC monograph set forth in a final order under section 505G for a therapeutic category of drugs describes the conditions, such as active ingredients, uses (indications), doses, routes of administration, labeling, and testing, under which OTC monograph drugs within such therapeutic category are generally recognized as safe and effective (GRASE) for their intended use. The conditions described in an OTC monograph may be amended, revoked, or otherwise modified in accordance with a final order issued under section 505G(b) of the FD&C Act.[2] Either FDA or a requestor[3] can initiate the order process in section 505G(b). A requestor can initiate the order process by submitting an OTC monograph order request[4] with respect to certain drugs, classes of drugs, or combinations of drugs.[5] FDA may opt to announce Data Requests described in this notice to help inform certain future OTC monograph drug activities, including development of FDA-initiated proposed orders.

II. Procedures for Data Requests

When FDA seeks data and information from the public to help inform certain OTC monograph drug activities, such as development of a potential FDA-initiated proposed order to add a GRASE condition to an OTC monograph, FDA intends to announce a Data Request on the OTC Monographs@FDA portal at *https://www.accessdata.fda.gov/scripts/cder/omuf/.* The Data Request will include instructions on the submission of the data and information to FDA, including

[1] Per section 744L(5) of the FD&C Act, an ''OTC monograph drug'' is defined as a nonprescription drug without an approved new drug application which is governed by the provisions of section 505G.

[2] Under section 505G(b)(1) of the FD&C Act, ''The Secretary may, on the initiative of the Secretary or at the request of one or more requestors, issue an administrative order determining whether there are conditions under which a specific drug, a class of drugs, or a combination of drugs, is determined to be . . . (i) not subject to section 503(b)(1) [*i.e.,* nonprescription]; and (ii) generally recognized as safe and effective under section 201(p)(1)''.

[3] Under section 505G(q)(3) of the FD&C Act (21 U.S.C. 355h(q)), the term *requestor* refers to any person or group of persons marketing, manufacturing, processing, or developing an OTC monograph drug.

[4] An OTC monograph order request means a request for an order submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

[5] See section 505G(b)(5) of the FD&C Act.

with respect to confidential information. The Data Request will also include instruction on how submissions may be viewed by the public. Additionally, interested parties and the public generally may sign up for FDA email mailing lists on the OTC Monographs@FDA portal to receive messages and alerts when FDA announces a Data Request described in this notice or other OTC monograph drug activities. FDA also intends to list future planned Data Requests of the type described in this notice in its Annual Forecast for Planned Monograph Activities, which is a nonbinding list issued each year of planned OTC monograph drug activities that FDA intends to initiate over the ensuing 3 years. It is available on the OTC Monographs@FDA portal.

This notice is not intended to announce the process with respect to requests for data to inform finalization of GRASE determinations for drugs described in section 505G(a)(3) of the FD&C Act (GRASE finalizations). The process FDA will use to request data packages to support GRASE finalizations will be announced in a future notice before any related crowdsourcing on that process, as described in the Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2026–2030 document (OMUFA II commitment letter).[6] In addition, this notice is unrelated to the following:

- any future **Federal Register** notice to solicit stakeholder feedback on test methods described in OTC monographs and the Test Methods Crowdsourcing described in section I.H of the OMUFA II commitment letter;
- the submission of relevant data and other information by a requestor (including a group of joint requestors) in an OTC monograph order request (OMOR)[7] submitted under section 505G(b)(5) of the FD&C Act;
- the requirement under section 505G(b)(2) of the FD&C Act to provide for a public comment period on a proposed order; and
- the requirement under section 505G(b)(4) of the FD&C Act, addressing certain expedited safety orders, to provide for a public comment period on an interim final order.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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[6] The OMUFA II commitment letter can be accessed at *https://www.fda.gov/media/182750/download.*

[7] OTC monograph order request (OMOR) is defined in section 744L(7) of the FD&C Act for purposes of user fees supporting FDA activities under section 505G of the FD&C Act and refers to a request for FDA to issue an administrative order pursuant to a request submitted under section 505G(b)(5) of the FD&C Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: Chimeric Antigen Receptors Targeting the Gamma Delta (γδ) T-Cell Receptor

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks research co-development partners and/or licensees for a set of Chimeric Antigen Receptors (CARs) that target the γδ T-Cell Receptor.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Andrew Burke, Ph.D. Senior Technology Transfer Manager at Email: *burkear@mail.nih.gov* or Phone: 240–276–5484.

SUPPLEMENTARY INFORMATION: T cells express two main types of receptors based on the proteins that make up the T-cell receptor (TCR) heterodimers: αβ (alpha beta) and γδ (gamma delta). T cells expressing the γδ TCR are detected at lower frequencies compared with T cells expressing the αβ TCR. γδ T cells make up 0.3–10% of peripheral blood T cells. The γδ TCR is expressed on the cell surface of several aggressive cancers, including—but not limited to—hepatosplenic T-cell lymphoma, primary cutaneous γδ T-cell lymphoma and T-cell acute lymphoblastic leukemia (T–ALL). These cancers carry poor prognosis as they are often resistant to chemotherapy. In addition, to their roles in cancer development, γδ T cells may also play role in autoimmune diseases, including psoriasis, rheumatoid arthritis, multiple sclerosis and myositis. There is evidence that γδ T cells are involved in initiation or persistence of these autoimmune diseases. To this end, new treatment options are needed for γδ T-cell malignancies and autoimmune diseases.

Researchers at the National Cancer Institute (NCI) have developed several CARs targeting the γδ TCR. These CARs can specifically bind to and immunologically recognize human γδ TCR. Binding of the CAR to the γδ TCR elicits an immune response that allows for killing of cells expressing this TCR.

''This Notice is in accordance with 37 CFR 404.4 Authority to grant licenses.''

NIH Reference Number: E–214–2024.

Related Technologies: N/A.

Product Type: Oncology | Immunology.

Therapeutic Area(s): Therapeutic.

Development Stage: Pre-clinical (*in vivo* validation).

Publications:

- Kochenderfer JN, et al. Development of Novel Chimeric Antigen Receptors Targeting the Gamma-Delta (γδ) T-Cell Receptor. (*https://doi.org/10.1182/blood-2024-204126*).

Patents: PCT/US2025/040252, filed August 1, 2025.

Potential Commercial Applications

- Enables the GMP production of personalized T cell therapy products targeting tumor specific mutations with a high percentage of engineered cells.

Competitive Advantages

- Increased therapeutic benefit due to enhanced persistence and performance following adoptive T cell transfer.
- Increased therapeutic benefit due to improved surface expression of the therapeutic TCR αβ.
  - TCR alpha/beta chains substantially eliminate the risk of mis-pairing with the endogenous alpha/beta chain sequences expressed by the host cell.
- Improved manufacturing since the population is highly enriched for the desired engineered cells.
  - Greatly increases the frequency of tumor-specific T cells following expansion, exceeding what is achieved using alternative methods to generate mutation- or tumor-specific T cells.

Collaboration Opportunity: Researchers at the NCI seek licensing for TCR-engineered T cells that will facilitate the ACT process.

Dated: July 13, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026–14344 Filed 7–15–26; 8:45 am]

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