

✓ Require that the contracting officer managing the contract with the largest total contract value be the responsible contracting officer to execute the novation agreement including a review by the government's legal counsel.

✓ Limit the list requested at FAR 42.1204(e)(2) to multiple year contracts identified at the time of submission of the request.

✓ Review the list of documentation being requested in light of the advancement of electronic records.

- For change-of-name agreements:

✓ Run the change-of-name process through SAM exclusively. Deem the name change automatically effective on all existing contracts and work orders and all pending submitted proposals via SAM.

✓ Limit the list requested at FAR 42.1205(a)(3) to multiple year contracts identified at the time of submission of the request.

✓ Explicitly permitting the electronic submission of change-of-name packages.

Response: The respondents' input is appreciated. The recommendations made by the commenters may be considered for future action. Any necessary revisions to FAR subpart 42.12, Novation and Change-of-Name Agreements, will be accomplished through rulemaking.

Comment: In the process of updating a legal entity name in SAM, Defense Logistics Agency (DLA) Commercial and Government Entity (CAGE) Review requires a signed statement from a contracting officer before an update to a contractor's CAGE will be made. At the same time, the responsible contracting officer requests that SAM be updated before issuing a novation or name change. This apparently irreconcilable administrative conflict causes delay in updating SAM resulting in more awards being issued against the original contractor that would need a modification. This creates additional burden for both the contractor and the government.

Response: If a contractor is changing its name in SAM—

1. After completing the steps required by FAR 42.1205, the contractor would have to update/renew its entire Entity Registration in SAM and should be able to upload either the signed Change-of-Name Agreement or the signed SF30, Modification of Contract, satisfying what's required by the DLA CAGE team for screening and validation. See SAM's Knowledge Base articles #KB 0016829 and KB 0016831.

2. Before completing the steps required by FAR 42.1205, the contractor—

a. Must provide the notification required by paragraph (d) of the FAR clause at 52.204–13, System for Award Management Maintenance.

b. Would have to update/renew its entire Entity Registration in SAM.

c. When SAM sends the CAGE for screening and validation to the CAGE team, the team may request legal documentation to support the name change. This could result in the contractor getting a request from the DLA CAGE team for the same documentation needed to complete the steps required by FAR 42.1205. See SAM's Knowledge Base article #KB 0016831.

3. But the contractor does not have any open federal government contracts, then, the contractor would have to update/renew its entire Entity Registration in SAM. The contractor must provide the legal documentation needed to support the name change to the CAGE team to complete the CAGE/SAM validation process.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 9000–0076, Novation and Change-of-Name Agreements.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Extension of the Application Deadline: The REACH Lark Galloway-Gilliam Award for Advancing Health Equity Challenge (REACH Lark Award Challenge)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On April 25, 2024, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), published in the **Federal Register** a notice announcing the 2024 Racial and Ethnic Approaches to Community Health (REACH) Lark Galloway-Gilliam for Advancing Health

Equity Award Challenge (REACH Lark Award Challenge). The CDC established a deadline date of June 21, 2024, for the transmittal of applications. This notice extends the deadline date for applications through July 12, 2024.

DATES: The Challenge will accept applications through July 12, 2024.

FOR FURTHER INFORMATION CONTACT: Stormie Israel, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Hwy. NE, Mailstop S107–5, Atlanta, GA 30341, Telephone: 770–488–2964, Email: dnpaopolicy@cdc.gov.

SUPPLEMENTARY INFORMATION:

Award Approving Official: Mandy K. Cohen, MD, MPH, Director, Centers for Disease Control and Prevention, and Administrator, Agency for Toxic Substances and Disease Registry.

On April 25, 2024, CDC published a **Federal Register** Notice (89 FR 31751) announcing the 2024 REACH Lark Award Challenge. The CDC established a deadline date of June 21, 2024, for the transmittal of applications. This notice extends the deadline date for transmittal of applications until July 12, 2024. CDC is extending the deadline to allow additional time for interested applicants to participate.

This biennial challenge was established in 2019 to recognize extraordinary individuals, organizations, or community coalitions associated with the REACH program whose work has contributed to the implementation of culturally tailored interventions that advance health equity, reduce health disparities, and increase community engagement to address preventable risk behaviors (e.g., tobacco use, poor nutrition, and physical inactivity).

To participate and submit an application, interested parties should go to <https://www.challenge.gov>. All information for this competition remains the same, except for the deadline for the transmittal of applications.

General Conditions

CDC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at CDC's sole discretion.

Participation in this Challenge constitutes an applicants' full and unconditional agreement to abide by the Challenge's Official Rules found at <https://www.Challenge.gov>.

Authority: 15 U.S.C. 3719.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2023-E-3105, FDA-2023-E-3106, FDA-2023-E-3109]

Determination of Regulatory Review Period for Purposes of Patent Extension; DAXXIFY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for DAXXIFY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 3, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 2, 2025. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 3, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 Nos. FDA-2023-E-3105, FDA-2023-E-3106, and FDA-2023-E-3109, for “Determination of Regulatory Review Period for Purposes of Patent Extension; DAXXIFY.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the