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.

FOR FURTHER INFORMATION CONTACT: Kunal Naik, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–8717.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 25, 2024 (89 FR 60436), FDA requested information and comments. Interested persons were originally given until September 23, 2024, to comment on evaluating and mitigating the immunogenicity risk of host cell proteins.

Following publication of the July 25, 2024, notice, FDA received a request to allow interested persons additional time to comment. The requester asserted that the time period of 60 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues.

II. Electronic Access

Persons with access to the internet may obtain relevant guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-pharmacology-considerations-peptide-drug-products.*

Dated: December 23, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31365 Filed 12–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5830]

Advisory Committee; Dermatologic and Ophthalmic Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Dermatologic and Ophthalmic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Dermatologic and Ophthalmic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 7, 2026, expiration date.

DATES: Authority for the Dermatologic and Ophthalmic Drugs Advisory Committee will expire on October 7, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–2855, *DODAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Dermatologic and Ophthalmic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

Pursuant to its charter, the Committee shall consist of a core of 12 voting members including 2 Chairpersons. Members and the Chairpersons are selected by the Commissioner or designee from among authorities knowledgeable in the fields of dermatology, ophthalmology, dentistry, immunology, epidemiology or statistics, and other related professions. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize

a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/dermatologic-and-ophthalmic-drugs-advisory-committee/dermatologic-and-ophthalmic-drugs-advisory-committee-charter* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: December 23, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31363 Filed 12–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Advanced Research Projects Agency for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This document announces that the Establishment of the Advanced Research Projects Agency for Health (ARPA–H) is being amended to reflect a revised organizational structure for ARPA–H that aligns with current statutory requirements. *See* 42 U.S.C. 290c(a)(2).

SUPPLEMENTARY INFORMATION: The Establishment of the Advanced Research Projects Agency for Health (ARPA–H) (May 24, 2022, at 87 FR 32174) should now read as follows:

Section I. Mission

The mission of ARPA–H is to (1) expand technical possibilities for the future of health, (2) forge a resilient health ecosystem to ensure optimal well-being for all, (3) drive scalable solutions to improve health care access and affordability, (4) build proactive health capacity to keep people from becoming patients, (5) foster data-driven innovation across the health ecosystem, and (6) increase the probability of successful transition.

Section II. Organization

ARPA–H consists of the following offices and personnel:

The ARPA–H Office of the Director

The ARPA–H Office of the Director (Director's Office (DIRO)) is comprised of:

1. The ARPA–H Director
2. Deputy Director
3. Chief of Staff
4. Such other staff as necessary to support the Office of the Director.

The ARPA–H Director is appointed by the President (42 U.S.C. 290c (1)) and reports directly to the Secretary of Health and Human Services. 42 U.S.C. 290c (3). The Secretary has delegated all determinations regarding ARPA–H programs and operations to be in the sole authority and discretion of the Director. Consistent with 42 U.S.C. 290c(c)(4)(B), this includes all decisions regarding the approval, termination and funding of all ARPA–H projects and programs.

DIRO's functions and responsibilities are as follows: (1) Oversee the creation of agency technical strategy, program approval, prioritization and implementation (2) Lead all aspects of internal Director's Office operations, including ongoing management of the agency's communications, legislative, governmental, legal, international, and mission office activities (3) Serve as the primary liaison for all Executive and Legislative functions of the organization, and fulfills principal level duties across HHS, including engagement with the Secretary and counselors (4) Serve as the primary liaison to Technical Staff, including program managers and their teams, and the Director's Advisory staff to ensure consistent and effective coordination and communication.

The Health Science Futures Office

The Health Science Futures Office (HSFO) is comprised of:

1. Director
2. Deputy Director
3. Such other staff as necessary to support the HSF Director.

The HSFO's functions and responsibilities are as follows: (1) Remove scientific and technological limitations that stymie our nation's progress toward new solutions for the health care of the future. (2) Cultivate novel, agile tools that will facilitate revolutionary advances in medical care. (3) Leverage the latest scientific breakthroughs and invests in the development of platforms and technologies that do not yet exist. (4) Propose agency-sponsored research programs to the ARPA–H Director, ensuring they align with strategic objectives.

The Resilient Systems Office

The Resilient Systems Office (RSO) is comprised of is comprised of:

1. Director
2. Deputy Director
3. Such other staff as necessary to support the RSO

RSO's mission and responsibilities are as follows: (1) Drive advances in health systems to improve their resilience, robustness, and interoperability, as well as their ability to adapt to unforeseen events, such as cyber-attacks, hospital closures, staffing shortages, emerging pathogens, and natural disasters. (2) Improve the continuity of care during regional and national emergencies, provides time savings to healthcare workforces, enhances quality of care across geographies, improves the robustness of clinical artificial intelligence (AI) applications, makes it easier for patients and clinicians to make informed decisions, and reduces gaps between advanced research and clinical care (3) Develop, implement, and manage novel, innovative scientific and technical programs aimed at improving health outcomes. (4) Propose agency-sponsored research programs to the ARPA–H Director, ensuring they align with strategic objectives.

The Scalable Solutions Office

The Scalable Solutions Office (SSO) is comprised of:

1. Director
2. Deputy Director
3. Such other staff as necessary to support the SSO.

SSO's functions and responsibilities are as follows: (1) Aim to improve health care access and affordability for all Americans by working with partners to streamline manufacturing processes, optimize distribution networks, and develop innovative delivery methods to bring critical health technologies and treatments to underserved communities and remote areas. (2) Focus on advancing research and development to create scalable health solutions, expanding the reach of proven technologies, and accelerating their integration into the healthcare system.