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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Elaine Chang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2169, Silver Spring, MD 20993–0002, 240–402–2628.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues.'' This guidance describes FDA's current recommendations regarding the overall development program and clinical trial designs for developing GnRH analogues to treat advanced prostate cancer.

This guidance finalizes the draft guidance of the same title issued on July 18, 2019 (84 FR 34400). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance included clarifying the scope of the guidance in the introduction section, adding recommendations on safety monitoring, and broadening recommendations on the appropriate trial population to include metastatic as well as biochemically recurrent disease rather than only metastatic.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by the OMB under the PRA. The collections of information in 21 CFR part 210 and 211, 21 CFR part 314, and 21 CFR part 601 have been approved under OMB control numbers 0910–0139, 0910–0001, and 0910–0338, respectively. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR 201.56 and 201.57 for the content and format of labeling for human prescription drug and biological products have been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 58 for good laboratory practice have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: May 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11410 Filed 5–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0589]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on July 28, 2022, from 9 a.m. to 5:45 p.m. Eastern Time and July 29, 2022, from 9 a.m. to 4 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions, including information regarding special accommodations due to a disability, may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm*.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–0589. The docket will close on August 29, 2022. Submit either electronic or written comments on this public meeting by August 29, 2022. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 29, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 29, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before July 11, 2022, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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 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 No. FDA–2022–N–0589 for ''General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA 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 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 the 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: Candace Nalls, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993–0002, 301–636–0510, *Candace.Nalls@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On July 28, 2022, the committee will discuss the topic of skin lesion analyzer technology and its application to detecting skin cancers in various patient care settings. The skin lesion analyzer devices on which the discussion is focused at this meeting are algorithm-based devices for adjunctive detection of various skin lesions, including skin cancers. We will refer to these computer algorithm-aided devices for adjunctive detection of lesions suspicious for skin cancers as Skin Lesion Analyzers (SLAs). In recent years, FDA has seen an increased interest in the development of skin lesion analyzers that employ artificial intelligence and machine learning. These devices include a range of technologies and intended user populations. FDA is interested in the committee members' perspectives on approaches for evaluating the performance of SLA devices given the heterogeneity of technologies and indications.

FDA is convening this committee to promote an open public discussion of, and seek expert opinion on, currently available scientific and clinical data pertaining to the diagnosing standard also known as ground truth, performance criteria, and patient population in future studies assisting medical providers in properly identifying skin lesions by a computer algorithm-aided device. The committee will be asked to discuss and provide recommendations regarding:

• The diagnosing standard, or ground truth, based on factual data that should be used as a comparison for the performance of diagnostic devices including, but not limited to, histology, consensus opinion of a panel of dermatologists, opinion of a single dermatologist, or other means.

• Acceptable thresholds for sensitivity and specificity based on the target diagnosis (melanoma, basal cell carcinoma (BCC), squamous cell carcinoma (SCC)), or on the intended user (dermatologist, primary care physician, lay user) if assessed for standalone performance.

• Patient characteristics, including lower or higher incidence populations, that should be tested before marketing.

• Balance of increased access with risk mitigation measures that are appropriate when the devices are used by lay people, by populations with very high or very low incidence of melanoma, by populations with low incidence, but high mortality associated with melanoma, or by the target diagnosis/lesion type (melanoma, BCC, SCC)

On July 29, 2022, the committee will discuss the possible reclassification of approved computer-aided melanoma detection class III devices: (1) MelaFind, a device that uses multispectral imaging and was approved in 2012 (P090012; *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p090012*), and (2) Nevisense, a device that measures impedance and was approved in 2017 (P150046; *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150046*).

Both Melafind and Nevisense devices are intended for use on cutaneous lesions suspicious for melanoma when a dermatologist chooses to obtain additional information when considering biopsy. The committee will discuss if there is sufficient information to reclassify computer-aided devices for adjunctive diagnostic information of lesions suspicious for melanoma from class III to class II, and what special controls may be appropriate to provide reasonable assurance of safety and effectiveness for these devices if they are reclassified as class II devices.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before July 11, 2022, will be provided to the panel. Oral presentations from the public will be scheduled on July 28, 2022, between approximately 1 p.m. and 2 p.m. Eastern Time, and on July 29, 2022, between approximately 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 28, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 29, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett, at *Artair.Mallett@fda.hhs.gov* or 301–796–9638, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11420 Filed 5–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Establishment of the Advanced Research Projects Agency for Health

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) has modified its structure. This notice announces the establishment of the Advanced Research Projects Agency for Health (or ARPA–H).

DATES: This reorganization was approved by the Secretary of Health and Human Services and takes effect May 24, 2022.

SUPPLEMENTARY INFORMATION: Part N, National Institutes of Health, of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS) (May 27, 1975 at 40 FR 22859, as amended most recently on November 3, 2004 at 69 FR 64081, and redesignated from Part HN as Part N on November 9, 1995 at 60 FR 56605, is amended as set forth below to implement ARPA–H.

Section N, *Organization and Functions* is amended as follows:

(1) Under *Grants Management Branch (NW83, formerly HNW83)* insert the following:

Advanced Research Projects Agency for Health (NY, formerly HNY). (1) Provides leadership for high-risk, high-reward biomedical and health research to speed application and implementation of health breakthroughs equitably. (2) Creates, supports, and manages programs to catalyze the development of transformative, evidenced-based, use-driven capabilities, platforms, and technologies in a range of biomedical and health research areas. (3) Facilitates partnerships and collaboration among government, academia, industry, and other sectors to accelerate the translation of innovation into meaningful and measurable benefits for the nation. (4) Converts use-driven research into tangible, sustainable solutions for patients.

Acquisition and Contracting Office (NY2, formerly HNY2). (1) Advises the ARPA–H Director and staff on acquisition and contract and grant financial advisory services. (2) Develops/implements ARPA–H policies, provides oversight, and manages the operational components in the areas of acquisition and contracts management, including other transactions. (3) Manages and conducts a comprehensive program of all research and development contracting, non-research and development contracting, ARPA–H support contracting, and commercial item acquisitions using simplified acquisition procedures, GSA Federal Supply Schedule acquisitions and simplified acquisitions. (4) Provides advice and assistance regarding all phases of the acquisition cycle from planning to closeout with the purpose of accomplishing all acquisitions needed for the scientific mission and all related acquisitions required by its customers.

Comptroller's Office (NY3, formerly HNY3). (1) Directs ARPA–H-wide budget policy, planning, analysis, formulation, and presentation, in collaboration with HHS Office of the Assistant Secretary for Financial Resources and NIH Office of Budget. (2) Manages the ARPA–H appropriated budget, including reprogramming and coordination of the use of the Director's Discretionary Fund and transfer authority. (3) Advises the ARPA–H Director and staff and provides leadership and direction for budgetary matters and financial management activities. (4) Develops policies and instructions for central services budget preparation and presentation. (5) Administers allocation of funds and manages a system of fund and budgetary controls. (6) Provides an ARPA–H manpower resource control system designed to allocate resources. (7) Provides, develops, and maintains an ARPA–H Management Account