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.

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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Denise Johnson-Lyles, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6469, Silver Spring, MD 20993–0002, 301–796–6169; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format.'' The final rule, *Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling,* referred to as the PLLR, which published December 4, 2014 (79 FR 72063), modified the labeling requirements for human prescription drug and biological products. The PLLR amended FDA's regulations governing the content and format of the ''Pregnancy,'' ''Labor and Delivery,'' and ''Nursing Mothers'' subsections of the ''Use in Specific Populations'' section of the existing labeling for human prescription drug and biological products. This guidance is intended to assist applicants in complying with the content and format requirements of the ''Pregnancy,'' ''Lactation,'' and ''Females and Males of Reproductive Potential'' subsections of labeling for human prescription drug and biological products, as described in the PLLR. This draft guidance revises the draft guidance of the same name issued December 4, 2014 (79 FR 72104). The revisions provide clarification and additional information on recommendations in response to public comments and the Agency's regulatory experience implementing the PLLR. Changes to this draft guidance from the previous draft guidance include the addition of the following:

- Information on formatting, omitting information, and pregnancy registries.
- Clarifying information related to the Risk Summary heading, risk statements, and human and animal data.
- Information on labeling for section 8.3 Females and Males of Reproductive Potential, including information on pregnancy testing, contraception, and infertility.
- Procedural information on implementation and submission of draft labeling to the Agency for review.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format.'' 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

FDA tentatively concludes that this draft guidance contains no collection 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.

However, this draft guidance refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA. The collection of information in 21 CFR 201.56 and 201.57 for preparing and submitting labeling has been approved under OMB control number 0910–0572. The collections of information in 21 CFR 314.70 and 314.97 for submitting supplements to an approved application, in 21 CFR 314.50(e) for submitting labeling for an application, and in 21 CFR 314.90 for submitting waiver requests for an application have been approved under OMB control number 0910–0001. The collection of information in 21 CFR 601.12 for submitting supplements to an approved application has been approved under OMB control number 0910–0338. In addition, the information collection provisions of the PLLR have been approved under OMB control number 0910–0624.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: July 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–16530 Filed 7–29–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Extension of Designation of Scarce Materials or Threatened Materials Subject to COVID–19 Hoarding Prevention Measures Under Executive Order 13910 and Section 102 of the Defense Production Act of 1950

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) provides notice of the extension of the designation issued March 25, 2020 under Executive Order 13910 (Executive Order) and section 102 of the Defense Production Act of 1950 (the Act), 50 U.S.C. 4512,

as amended, designating health and medical resources necessary to respond to the spread of the virus associated with Coronavirus Disease 2019 (COVID–19) that are scarce or the supply of which would be threatened by excessive accumulation by people or entities not needing the excess supplies (March 25 Designation Notice). These designated materials are subject to the hoarding prevention measures authorized under the Executive Order and the Act. The March 25 Designation Notice was subsequently published in the **Federal Register** on March 30, 2020. *See* 85 FR 17592. On June 30, 2020, HHS updated the March 25 Designation Notice to change the information contact and to remove chloroquine phosphate and hydroxychloroquine HCl as a scarce or threated material. This update was published in the **Federal Register** on July 7, 2020. *See* 85 FR 40667. Without extension, the March 25 Designation Notice would terminate 120 days from publication. This notice, issued on July 23, 2020, extends the March 25 Designation Notice for an additional 120 days. This notice also includes modifications and additions to the original list of scarce or threatened materials.

DATES: This action took effect July 23, 2020 and terminates January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Paige Ezernack: 202–260–0365; *PaigeEzernack@hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 23, 2020, and in response to the spread of the virus associated with COVID–19, President Trump signed Executive Order 13910 (Executive Order) to prevent hoarding of health and medical resources necessary to respond to the spread of COVID–19 within the United States. As provided in the Executive Order, it is the policy of the United States that health and medical resources needed to respond to the spread of COVID–19, such as personal protective equipment and sanitizing and disinfecting products, are appropriately distributed. This policy furthers the goal of protecting the Nation's healthcare systems from undue strain.

Through the Executive Order, the President delegated, to the Secretary of Health and Human Services (the Secretary), his authority under section 102 of the Defense Production Act of 1950, 50 U.S.C. 4512, as amended (the Act), to prevent hoarding of health and medical resources necessary to respond to the spread of COVID–19 within the United States, and his authority to implement the Act in subsection III of chapter 55 of title 50, United States Code (50 U.S.C. 4554, 4555, 4556, and 4660). Under this delegation and the Act, the Secretary may designate such resources as scarce materials or materials the supply of which would be threatened by such accumulation (threatened materials). The Secretary may also prescribe conditions with respect to accumulation of such materials in excess of the reasonable demands of business, personal, or home consumption. The Act prohibits any person or entity from accumulating designated materials (1) in excess of the reasonable demands of business, personal, or home consumption, or (2) for the purpose of resale at prices in excess of prevailing market prices.

The March 25 Designation Notice issued by HHS designates scarce materials or threatened materials that are subject to the hoarding prevention measures authorized under the Executive Order and the Act. *See* 85 FR 17592 (Mar. 30, 2020). Under 50 U.S.C. 4552(13), the term ''materials'' includes ''(A) any raw materials (including minerals, metals, and advanced processed materials), commodities, articles, components (including critical components), products, and items of supply; and (B) any technical information or services ancillary to the use of any such materials, commodities, articles, components, products, or items.'' For purposes of the March 25 Designation Notice, the term ''scarce materials or threatened materials'' means health or medical resources, or any of their essential components, determined by the Secretary to be needed to respond to the spread of COVID–19 and which are, or are likely to be, in short supply or the supply of which would be threatened by hoarding. 85 FR at 17592. Designated scarce materials or threatened materials are subject to periodic review by the Secretary.

The designation is not a ''regulation'' under the Administrative Procedure Act (APA). *See* 50 U.S.C. 4559 (providing an exemption from the APA). To the extent that it were, the Secretary finds that, in light of the current global pandemic, urgent and compelling circumstances make compliance with public comment requirements impracticable. *See id.*

The March 25 Designation Notice was scheduled to terminate after 120 days from the date of publication, unless superseded by a subsequent notice. Given the ongoing pandemic, the Secretary finds good cause to extend the March 25 Designation Notice, as modified by the June 30, 2020 notice, for an additional 120 days. The Secretary also finds good cause to include the following modifications and additions to list of scarce or threatened materials:

1. Add ''laboratory reagents and materials used for isolation of viral genetic material and testing, such as transport media, collection swabs, test kits and reagents specific to those kits, and consumables such as plastic pipette tips and plastic tubes'';
2. Add ''drug products currently recommended by the NIH COVID–19 Treatment Guidelines Panel, including (as of July 23, 2020) remdesivir and dexamethasone''; and
3. Add ''alcohol-based hand sanitizer and rubs.''

A copy of the Notice of the March 25 Designation, including the above modifications and additions and as modified by the June 30, 2020 notice, is provided below and also can be found on HHS's website.

Notice of Designation of Scarce Materials or Threatened Materials

Health or medical resources, or any of their essential components, determined by the Secretary of HHS to be needed to respond to the spread of COVID–19 and which are, or are likely to be, in short supply (scarce materials) or the supply of which would be threatened by hoarding (threatened materials). Designated scarce materials or threatened materials are subject to periodic review by the Secretary.

The following materials are designated pursuant to section 102 of the Defense Production Act (50 U.S.C. 4512) and Executive Order 13190 of March 23, 2020 (Preventing Hoarding of Health and Medical Resources to Respond to the Spread of COVID–19) as scarce materials or threatened materials:

1. N–95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates
2. Other Filtering Facepiece Respirators (*e.g.,* those designated as N99, N100, R95, R99, R100, or P95, P99, P100), including single-use, disposable half-mask respiratory protective devices that cover the user's airway (nose and mouth) and offer protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181
3. Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges
4. Powered Air Purifying Respirator (PAPR)
5. Portable Ventilators, including portable devices intended to

mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas
6. Sterilization services for any device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act and sterilizers as defined in 21 CFR 880.6860, 880.6870, and 880.6880, including devices that already have FDA marketing authorization and those that do not have FDA marketing authorization but are intended for the same uses
7. Disinfecting devices intended to kill pathogens and other kinds of microorganisms by chemical means or physical means, including those defined in 21 CFR 876.1500, 880.6992, and 892.1570 and other sanitizing and disinfecting products suitable for use in a clinical setting
8. Medical gowns or apparel, *e.g.,* surgical gowns or isolation gowns
9. Personal protective equipment (PPE) coveralls, *e.g.,* Tyvek Suits
10. PPE face masks, including any masks that cover the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels
11. PPE surgical masks, including masks that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials
12. PPE face shields, including those defined at 21 CFR 878.4040 and those intended for the same purpose
13. PPE gloves or surgical gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such gloves intended for the same purposes
14. Ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as ''ventilators''), ventilator tubing connectors, and ventilator accessories as those terms are described in FDA's March 2020 Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency located at *https://www.fda.gov/media/136318/download*
15. Laboratory reagents and materials used for isolation of viral genetic material and testing, such as transport media, collection swabs, test kits and reagents specific to those kits, and consumables such as plastic pipette tips and plastic tubes
16. Drug products currently recommended by the NIH COVID–19 Treatment Guidelines Panel, including (as of July 23, 2020) remdesivir and dexamethasone
17. Alcohol-based hand sanitizer and rubs

Authority

The authority for this Notice is Executive Order 13910 and section 102 of the Defense Production Act of 1950, 50 U.S.C. 4512, as amended.

Dated: July 23, 2020.

Ann C. Agnew,

Executive Secretary, Department of Health and Human Services.

[FR Doc. 2020–16458 Filed 7–27–20; 4:15 pm]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). The meeting will be open to the public via webex and teleconference; a pre-registered public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting via webex/teleconference. Individuals who wish to send in their pre-recorded or written public comments should send an email to *CARB@hhs.gov*. Registration information is available on the website *http://www.hhs.gov/paccarb* and must be completed by September 2, 2020. Additional information about registering for the meeting and providing public comment can be obtained at *http://www.hhs.gov/paccarb* on the Meetings page.

DATES: The meeting is scheduled to be held on September 9, 2020, from 12:00 p.m. to 3:30 p.m. and September 10, 2020, from 12:00 p.m. to 3:30 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the PACCARB at *http://www.hhs.gov/paccarb* when this information becomes available. Pre-registration for attending the meeting is required to be completed no later than September 2, 2020.

ADDRESSES: Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

FOR FURTHER INFORMATION CONTACT: Jomana Musmar, M.S., Ph.D., Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room L616, Switzer Building, 330 C. St. SW, Washington, DC 20201. Phone: 202–746–1512; Email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), established by Executive Order 13676, is continued by Section 505 of Public Law 116–22, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Activities and duties of the Advisory Council are governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The PACCARB shall advise and provide information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The PACCARB shall function solely for advisory purposes.

Such advice, information, and recommendations may be related to improving: The effectiveness of antibiotics; research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities; surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics; education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals; methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and coordination with respect to international efforts in