CDRH and CBER and the formal meetings used in CDER and CBER, or through CPAMs, as appropriate.

FDA is publishing this guidance consistent with the Agency's ongoing commitment to enhancing clarity and transparency regarding regulatory considerations for combination products, and in accordance with the mandate under section 503(g)(8)(C)(vi) of the Federal Food, Drug, and Cosmetics Act (FD&C Act) (21 U.S.C. 353(g)(8)(C)(vi)), which was added by section 3038 of the 21st Century Cures Act (Pub. L. 114–255). Section 503(g)(8)(C)(vi) of the FD&C Act requires FDA to issue a final guidance addressing: (1) The structured process for managing pre-submission interactions with sponsors developing combination products; (2) best practices to ensure FDA feedback in such pre-submission interactions represents the Agency's best advice based on the information provided during these pre-submission interactions; and (3) how CPAMs relate to other FDA meeting types, what information should be submitted prior to a CPAM, and the form and content of agreements reached through a CPAM.

In response to comments received on the draft guidance, this final guidance includes additional information on use of CPAMs and application-based mechanisms. The guidance also provides additional clarity on how CPAMs will be conducted, including expected timelines for CPAM-related activities.

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 ''Requesting FDA Feedback on Combination Products.'' 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 OMB under the PRA. The collections of information pertaining to orphan drug provisions in 21 CFR part 316 are approved under OMB control number 0910–0167; the collections of information pertaining to investigational device exemption submission provisions in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information pertaining to investigational new drug submission provisions in 21 CFR part 312 are approved under OMB control number 0910–0014; the collections of information pertaining to biologics licensing submission provisions in 21 CFR part 601 are approved under OMB control number 0910–0338; and the collections of information pertaining to combination product agreement meetings are approved under OMB control number 0910–0523.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/combination-products/guidance-regulatory-information/combination-products-guidance-documents* or *https://www.regulations.gov.*

Dated: November 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26700 Filed 12–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1768]

Advisory Committee; Pharmacy Compounding Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Pharmacy Compounding 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 Pharmacy Compounding Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until April 25, 2022.

DATES: Authority for the Pharmacy Compounding Advisory Committee will expire on April 25, 2022, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Yvette Waples, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *PCAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3, FDA is announcing the renewal of the Pharmacy Compounding Advisory Committee (Committee). The Committee is a non-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 compounding drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee shall provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a and 353b), and, as required, any other product for which FDA has regulatory responsibility and make 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 the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. These members will include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one or more technically qualified members, selected by the Commissioner or designee, who are identified with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one or more non-voting representative members who are identified with industry interests. There

may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/pharmacy-compounding-advisory-committee/pharmacy-compounding-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 document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: November 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26696 Filed 12–3–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2216]

Revocation of Authorizations of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocations of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Manufacturers of Protective Barrier Enclosures and Other Stakeholders for certain protective barrier enclosures (''PBE Authorization'') and to Manufacturers of Infusion Pumps and Infusion Pump Accessories and Other Stakeholders for certain infusion pumps and infusion pump accessories (''Infusion Pump Authorization''). FDA revoked the PBE Authorization on August 20, 2020, and the Infusion Pump Authorization on September 21, 2020, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The PBE Authorization is revoked as of August 20, 2020. The Infusion Pump Authorization is revoked as of September 21, 2020.

ADDRESSES: Submit written requests for single copies of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On May 1, 2020, FDA issued the PBE Authorization. On May 13, 2020, FDA issued the Infusion Pump Authorization. Of note, these were both ''umbrella'' Authorizations, *i.e.,* for certain types of products that met the requirements as described in their respective Authorizations. Any product with an individual Authorization is not affected by revocation of these two umbrella Authorizations. Notice of the issuance of the Authorizations was published in the **Federal Register** on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. Subsequent to the issuance of the PBE Authorization, FDA considered new information, specifically from new preliminary evidence from simulated intubation procedure models of potential adverse events that could occur or complications with protective barrier enclosures without negative pressure. Subsequent to the issuance of the Infusion Pump Authorization, FDA considered that no device had been listed under the EUA and that circumstances instead support allowing for tailored requirements of authorization in individual EUAs.

II. EUA Criteria for Issuance No Longer Met and Other Circumstances Make Revocation Appropriate To Protect the Public Health or Safety

Under section 564(g)(2)(B) and (C) of the FD&C Act, the Secretary of the Department of Health and Human Services may revoke an EUA if, among other things, the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public health or safety. On August 20, 2020, FDA revoked the PBE Authorization because the criteria for issuance were no longer met and other circumstances make such revocation appropriate to protect the public health or safety. Under section 564(c)(2) of the FD&C Act, an EUA may be issued only if FDA concludes that, based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing such disease or condition and that the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product.

Given the new preliminary evidence from simulated intubation procedure models of potential adverse events that could occur or complications with protective barrier enclosures without negative pressure recently reported in literature articles, FDA has concluded it is not reasonable to believe the product may be effective in decreasing healthcare provider exposure to airborne particles and may instead contribute to an increase in healthcare provider exposure to airborne particles. Additionally, the literature articles note potential risks of protective barrier enclosures, such as increased intubation times, lower first-pass intubation success rates, damage to personal protective equipment from intubation boxes, particles escaping from intubation boxes through arm access holes reaching the face of the healthcare provider performing the endotracheal intubation, and human factors issues contributing to increased endotracheal intubation times. Further, based on the same information and the risks to public health, including from the device's potential contribution to an increase in healthcare provider exposure to airborne particles, FDA has concluded under section 564(g)(2)(C) of the FD&C Act that other circumstances make revocation appropriate to protect the public health or safety. Accordingly, FDA has revoked the PBE