

C. CDRH Guidance

While this guidance contains no collection of information, it does refer to previously approved FDA collections of

information (listed in table 4). Therefore, clearance by OMB under the 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 in the following FDA regulations have been approved by OMB as listed in the following table:

TABLE 4—CDRH GUIDANCE AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control No(s).
Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (January 2021).	800, 801, and 809 807, subparts A through D 807, subpart E 803 806 820	0910–0485. 0910–0625. 0910–0120. 0910–0437. 0910–0359. 0910–0073.

IV. Electronic Access

Persons with access to the internet may obtain COVID–19-related guidances at:

- FDA web page entitled “COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>;
- FDA web page entitled “Search for FDA Guidance Documents” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>; or
- <https://www.regulations.gov>.

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2253]

Medical Device User Fees; Stakeholder Meetings on Medical Device User Fee Amendments of Fiscal Years 2023 to 2027 Reauthorization; Request for Notification of Stakeholder Intention to Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders—including patient and

consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Medical Device User Fee Amendments (MDUFA). The statutory authority for MDUFA expires in September 2022. At that time, new legislation will be required for FDA to continue collecting user fees for the medical device program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next MDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups during FDA’s negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent public stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by February 26, 2021. Stakeholder meetings will be held monthly. It is anticipated that they will commence in March 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The meetings will take place virtually and will be held by webcast only. Submit notification of intention to participate in monthly stakeholder meetings by email to MDUFARReauthorization@fda.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Ellen Olson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1664, Silver Spring, MD 20993, 301–796–4322, MDUFARReauthorization@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of MDUFA. MDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of medical devices. The authorization for the current program (MDUFA IV) expires in September 2022. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the medical device review process.

Section 738A(b)(1) of the FD&C Act (21 U.S.C. 379j–1(b)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts, in developing recommendations for the next MDUFA program. FDA initiated the reauthorization process by holding a public meeting on October 27, 2020, where stakeholders and other members of the public were given an opportunity to present their views on the reauthorization. The FD&C Act further requires that FDA continue meeting with the representatives of patient and consumer advocacy groups at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization and their suggestions for changes. It is anticipated that these monthly stakeholder consultation meetings will commence in March 2021.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer advocacy groups, healthcare professional associations, as well as

scientific and academic experts, notify FDA of their intent to participate in the periodic stakeholder consultation meetings on MDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in the stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice, and are otherwise eligible to attend, may participate in all stakeholder consultation discussions while FDA negotiates with the regulated industry. These stakeholder discussions will satisfy the consultation requirement in section 738A(b)(3) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding MDUFA reauthorization, please provide notification by email to MDUFAVReauthorization@fda.hhs.gov by February 26, 2021. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting from FDA after the Agency receives this notification.

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2305]

Authorizations of Emergency Use of Certain Drug and Biological Products During the COVID-19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of five Emergency Use

Authorizations (EUs) (the Authorizations) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for drug and biological products for use during the COVID-19 pandemic. FDA issued one Authorization for a drug as requested by Baxter Healthcare Corporation (Baxter); one Authorization for a biological product as requested by the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (ASPR/HHS); an Authorization for a drug and an Authorization for a biological product as requested by Eli Lilly and Company; and one Authorization for biological products as requested by Regeneron Pharmaceuticals, Inc. The Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by the Secretary of HHS that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS-CoV-2, causes the illness COVID-19. On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to the FD&C Act, subject to the terms of any authorization issued under that section. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorization for Baxter is effective as of August 13, 2020; the Authorization for ASPR/HHS is effective as of August 23, 2020; the Authorizations for Eli Lilly and Company are effective as of November 9, 2020, and November 19, 2020, respectively; and the Authorization for Regeneron Pharmaceuticals, Inc. is effective as of November 21, 2020.

ADDRESSES: Submit written requests for single copies of the EUs 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 Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of

Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993-0002, 301-796-8510 (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. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces;¹ (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living

¹ In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.