• SCONE Medical Solutions Inc.'s SCONE, issued December 18, 2020; [19]

• Siemens Healthcare Diagnostics Inc.'s ADVIA Centaur IL6 assay, issued December 18, 2020; [20]

• Yale New Haven Health System's Yale New Haven Health FILTERING FACEPIECE RESPIRATOR Decontamination System, issued January 15, 2021; [21] and

• Everlywell, Inc.'s Everlywell COVID–19 Test Home Collection Kit DTC, issued February 13, 2021.[22]

Dated: April 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–08467 Filed 4–22–21; 8:45 am]

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FDA, it is reasonable to believe that the Bioquell Technology System may be effective at decontaminating compatible N95 respirators for single-user reuse by healthcare providers to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the Bioquell Technology System for decontaminating compatible N95 respirators for single-user reuse by healthcare providers to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates during filtering facepiece respirator shortages during the COVID–19 pandemic.

[19] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that SCONE may be effective in preventing healthcare providers exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment, at the time of definitive airway management, when performing airway-related medical procedures, or during certain transport for a maximum duration of use of 30 minutes, of patients with suspected or confirmed diagnosis of COVID–19 and that the known and potential benefits of SCONE for such use outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of SCONE.

[20] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in treating COVID–19, by assisting in identifying severe inflammatory response in patients with confirmed COVID–19 illness to aid in determining the risk of intubation with mechanical ventilation, and that the known and potential benefits of the product when used for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[21] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Yale New Haven Health filtering facepiece respirator decontamination system may be effective at decontaminating compatible N95 respirators for multiple-user reuse by healthcare providers to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the Yale New Haven Health filtering facepiece respirator Decontamination System for decontaminating compatible N95 respirators for multiple-user reuse by healthcare providers to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates during filtering facepiece respirator shortages during the COVID–19 pandemic.

[22] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the home-collected human specimen, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of the product and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0001]

Model Informed Drug Development Approaches for Immunogenicity Assessments; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research, in collaboration with the Center for Drug Evaluation and Research, is announcing the following public workshop entitled ''Model Informed Drug Development Approaches for Immunogenicity Assessments.'' The purpose of this public workshop is to discuss the best practices and future directions of quantitative methods for predicting immunogenicity of biological products. This public workshop is also being conducted to satisfy one of FDA's performance goals included in the sixth reauthorization of the Prescription Drug User Fee Amendments (PDUFA VI), part of the FDA Reauthorization Act of 2017 (FDARA), to hold a series of workshops related to model-informed drug development (MIDD).

DATES: The public workshop will be held virtually on June 9, 2021, from 8 a.m. to 5 p.m., Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all participants will be joining this public workshop via an online teleconferencing platform. The public workshop will be held virtually via Adobe Connect. Webcast information will be provided upon completion of registration.

FOR FURTHER INFORMATION CONTACT: Loni Warren Henderson or Sherri Revell, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1118, Silver Spring, MD 20993, 240–402–8010, *CBERPublicEvents@fda.hhs.gov* (subject line: MIDD Workshop).

SUPPLEMENTARY INFORMATION:

I. Background

Under FDARA, and in accordance with section I, part J of the PDUFA VI Performance Goals, FDA agreed to convene a series of workshops to identify best practices for MIDD (*https://www.fda.gov/media/99140/download,* see page 27). Each workshop focuses on current and emerging scientific approaches, including methodological limitations. The workshop announced in this notice fulfills FDA's performance commitment under PDUFA VI, specifically for modeling immunogenicity and correlates of protection for evaluating biological products, including vaccines and blood products.

II. Topics for Discussion at the Public Workshop

Topics for discussion include the following:

1. Current in silico methodologies used to assess drug immunogenicity;
2. Available data resources and data needs for MIDD approaches to evaluate immunogenicity at various stages of drug development;
3. Possible applications and limitations of MIDD approaches for desired immunogenicity of vaccine/allergenic products; and
4. Insight into the possible future applications of MIDD and good modeling practices.

A detailed agenda will be posted in advance of the workshop at *https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/workshops-meetings-conferences-biologics.*

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register online by May 26, 2021, at *https://www.eventbrite.com/e/model-informed-drug-development-approaches-for-immunogenicity-assessments-tickets-138618787525.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration is free and based on space availability, with priority given to early registrants.

If you need special accommodations due to a disability, please contact Loni Warren Henderson or Sherri Revell (see **FOR FURTHER INFORMATION CONTACT**) no later than May 26, 2021. Please note, Computer Aided Realtime Translation/captioning will be available.

Streaming Webcast of the Public Workshop: This public workshop will be streamed via webcast only.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. A link to the transcript will also be available on the internet at *https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/workshops-meetings-conferences-biologics.*

Dated: April 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–08487 Filed 4–22–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0190]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by May 24, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0256. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Infant Formula Requirements—21 CFR parts 106 and 107

OMB Control Number 0910–0256—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (FD&C Act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify us when infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. We have issued regulations to implement the FD&C Act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). We also regulate the labeling of infant formula under the authority of section 403 of the FD&C Act (21 U.S.C. 343). Under our labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. Failure to comply with any of the applicable labeling regulations will render an infant formula misbranded under section 403 of the FD&C Act. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately.

While the infant formula regulations help ensure the consistent production of safe and nutritionally adequate infant formulas for healthy term infants, they apply with one narrow exception. Section 412(h)(1) of the FD&C Act exempts an infant formula represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of subsections 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as ''exempt infant formulas.'' Section 412(h)(2) of the FD&C Act authorizes us to establish terms and conditions for the exemption of an infant formula from the requirements of subsections 412(a), (b), and (c) of the FD&C Act.

In support of exempt infant formulas, we have issued the Agency guidance document entitled ''Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports.'' The guidance document includes our recommendation that manufacturers of exempt infant formulas follow, to the extent practicable, subparts A, B, C, D, and F of 21 CFR part 106, and is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exempt-infant-formula-production.*

We have also developed electronic Form FDA 3978 (Infant Formula Tracking System (IFTRACK)) so that infant formula manufacturers may electronically submit reports and notifications in a standardized format to FDA. However, manufacturers that prefer to submit paper submissions in a