MOU 225-16-008

MEMORANDUM OF UNDERSTANDING BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION FOR COORDINATION REGARDING EMERGENCY USE INSTRUCTIONS FOR MEDICAL COUNTERMEASURES

I. PURPOSE

This Memorandum of Understanding (MOU) between the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) (singularly, "agency," and collectively, "agencies,") establishes a framework for the agencies' coordination in support of CDC's use of its delegated authority to develop and issue emergency use instructions (EUI) for eligible medical countermeasures (MCMs).[1]

II. AUTHORITY

FDA has the authority to enter into this agreement pursuant to sections 1003(b) and (c) of the Federal Food, Drug, and Cosmetic (FD&C) Act 21 U.S.C. sections 303(B) and c(c)).

CDC has the authority to enter into this agreement pursuant to sections 301 and 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. Section 241 and 247d-6b).

III. BACKGROUND

FDA and CDC are agencies within the Department of Health and Human Services (HHS) with a common public health mission.

FDA is responsible for protecting the public health through the regulation of food, cosmetics, tobacco, and medical products, including drugs, biological products, animal drugs, and medical devices. FDA administers the FD&C Act and relevant sections of the PHS Act, among other statutes. Among its duties, FDA reviews applications for approval, licensure, or clearance to market medical products; regulates the use of marketed medical products; regulates the use of investigational products and related research; and authorizes the emergency use of MCMs for
chemical, biological, radiological, or nuclear (CNRN) threats or emergencies, including novel or emerging infectious disease threats (e.g., pandemic influenza).

CDC's mission is to collaborate with public health partners through health promotion;

disease, injury, and disability prevention; and emergency preparedness to create the expertise, information, and tools that people and communities need to protect their health. CDC Works with partners throughout the nation and the world to monitor public health, detect and investigate health problems, conduct research and to enhance prevention, develop and advocate sound public health policies implement prevention strategies, promote healthy behaviors, foster safe and healthful environments, and provide leadership and training. CDC conducts its activities under the authority of the PHS Act and other relevant federal statutes.

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 [2] added section 564A(e) to the FD&C Act to allow a designated official within HHS to create and issue EUI concerning an eligible MCM's approved, licensed, or cleared conditions of use before or during a CBRN event. Although the EUI authority is part of the FD&C Act, on the joint recommendation of FDA, CDC, and the HHS Assistant Secretary for Preparedness and Response, the Secretary of HHS delegated this authority to CDC. [3] Government stakeholders (e.g., Federal, State, local, and tribal governments), or persons acting on their behalf, may disseminate EUI both before a CBRN event occurs, in preparation for an emergency response, and during a response to a CBRN event.

IV. SUBSTANCE OF AGREEMENT AND RESPONSIBILITIES OF EACH AGENCY

A. Coordination Regarding Development and Issuance Of EUI:

1. FDA and CDC recognize that the intent of section 564A(e) is to allow for the development and dissemination of EUI concerning a disease or condition for which the eligible MCM has been approved, licensed, or cleared by the FDA. Products distributed and used in accordance with a CDC issues EUI will not be considered by FDA to be an unapproved product or deemed misbranded or adulterated when used during specific emergency circumstances or in preparation for a an emergency response. [4][5]

2. The agencies agree that CDC's use of this authority is consistent with CDC's clinical expertise in providing event-driven prevention and treatment recommendations, facilitating emergency preparedness and response activities, including coordination and communication with other government stakeholders on MCL issues, as well as its front-line role in managing the Strategic National Stockpile of products.

a. CDC will identify MCMs that meet the following prerequisite criteria from which development and issuance of EUI may be appropriate.

i. The MCM is FDA-approved, licensed, or cleared under sections 505, 510(k), or 515 of the FD&C Act or section 351 of the PHS Act, as applicable, AND

ii. The Intended EUI for the eligible MCM concerns the product's FDA-approved licensed, or

cleared conditions of use.

b. For Eligible MCMs that meet these prerequisites, CDC will consider developing EUI based on the following factors:

i. The emergency use necessitates instructions and information that deviate from approved labeling, standard clinical practice, and/or standard medical modality (e.g., individual prescription within the patient-clinician relationship).

ii. For any EUI that require consideration of additional, relevant data or information to assess risk versus benefit of the proposed emergency use, CDC will consider availability of any published data, any data or information provide to CDC by FDA, and any existing CDC recommendations.

c. If CDC were to believe that a proposed use of an MCM presents risk for which no available data or information is available or for which substantial analysis of data or information is necessary, then CDC may recommend consideration of an investigational New Drug application (IND), Investigational Device Exemption (IDE), or Emergency Use Authorization (EUA) to provide instructions for the proposed emergency use of the MCM.

3. FDA and CDC further recognize that FDA often has the most recent data and information, which may not be publicly accessible, to assess the risks and benefits of a proposed used of an eligible MCM under CDC's consideration. There, before CDC's issuance (or reissuance) of EUI, CDC expects to consult with FDA, and FDA expects to share with CDC (to the extent feasible in light of any emergency circumstances that may exist), any data or information available to FDA that would be relevant to the proposed EUI.

4. CDC agrees to notify FDA when EUI are issued and make them available to FDA. When needed for specific preparedness and emergency response needs and to the extent feasible and appropriate, FDA and CDC agree to coordinate issuance of EUI with other activities authorized in section 564A of the FD&C Act, such as FDA's issuance of emergency dispensing orders or waivers of Current God Manufacturing Practice requirements.

5. Each agency has designated the following central contact points to address communications from the other agency dealing with matters covered by this agreement:

For CDC:

Drugs and Biologics
Yon Yu, Pharm.D.
Associate Director for Regulatory Affairs
Office of the Director
NCEZID/CDC

404-639-3046
Fkb8@cdc.gov (mailto:Fkb8@cdc.gov)

In vitro Diagnostics
Laura Rose
Regulatory Affairs Team Lead
Laboratory Preparedness and Response Brach
Division of Preparedness and Emerging Infections, NCEZID/CDC
404-639-1084
Zey9@cdc.gov (mailto:Zey9@cdc.gov)

For FDA:
Elizabeth Sadove, JD
Director, MCM Regulatory Policy
OCET/OCS/FDA
301-796-8515
elizabeth.sadove@fda.hhs.gov (mailto:elizabeth.sadove@fda.hhs.gov)

6. The agencies anticipate that consultation may involve more than one interaction -- particularly in the event that EUI are developed or revised over time -- to ensure that CDC has the most up-to-date product information that FDA may share. FDA and CDC agree to respond promptly to inquiries or other communications from one another, taking into account the urgency of the inquiry and any attendant circumstances.

7. FDA and CDC will meet periodically to promote communication and understanding of relevant statutory responsibilities, regulations, and policies, to serve as a forum for questions and problems that may arise concerning general matters covered by this agreement, and to establish any additional, specific procedures and safeguards necessary to implement this MOU.

8. Each agency will notify the other agency as soon as possible when issues of mutual concern become evident.

B. Confidentiality

1. FDA and CDC recognize and agree that information exchanged under this MOU that contains any of the following types of information must be protected from unauthorized use and disclosure: (1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(C) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their

implementing regulations (e.g., Trade Secrets Act (18 USC 1905)), the Privacy Act (5 USC 552a), other FOIA exemptions not mentioned above (5 USC 552(b)), the FD&C Act (21 USC 301 et seq.), the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191), Section 319L(e) of the PHS Act (42 U.S.C. 247d-7e(e)), and disclosure restrictions subject to 41 U.S.C. 2101-2107 (Procurement Integrity Act) and 48 CFR 3.104 (Federal Acquisition Regulation).

2. Both parties will establish safeguards to ensure that any nonpublic information shared under this MOU is protected from unauthorized disclosure or use, and should include the marking of any materials as "confidential": prior to disclosure or the use of encryption technologies when appropriate. Information consisting of confidential commercial information or trade secrets may be shared pursuant to the procedures set forth in 1) the Memorandum of Understanding Between the Food and Drug Administration and the Centers for Disease Control and Prevention, which describes information sharing procedures between FDA and CDC (FDA MOU No. 225-24-0017 [6] or 2) the Memorandum of Understanding Concerning Information-Sharing Exchanges Involving FDA Among Agencies Participating in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) (FDA MOU No. 225-13-013), which requires that each individual receiving such information shall be required, prior to receiving any such information, to sign a confidentiality commitment in the form attached as Exhibit B to MOU 225-13-013. [7]

3. Each agency agrees to promptly notify the other of any actual or suspected unauthorized disclosure of information shared under this MOU.

4. If records provided by either party under this agreement are the subject of a FOIA request submitted to the party that received the records, that party will refer the FOIA request and relevant records to the party that provided the records for processing. If the FOIA request seeks both parties' records or if the request is for records created by one party that incorporates information provided by the other party, in accordance with the HHS FOIA regulations at 45 CFR 5, the party receiving the FOIA request will forward all such requests to the respective FOIA offices for disposition.

V. GENERAL PROVISIONS

This is an internal Government agreement between the parties to this MOU and does not confer any rights or benefits to any person or party. This MOU does not include any commitment, by either agency, of resource contributions or exchanges.

This MOU does not supersede any existing agreements or arrangements between the parties; to the extent the provisions of this MOU conflict with any existing or future agreement between FDA and CDC, the provisions of this MOU shall govern FDA and CDC communications relating to the creation and issuance of EUI pursuant to section 564A(e) of

the FD&C Act. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the parties operate and nothing in the MOU shall be construed as changing the current requirements under the statutes and regulations administered and enforced by either agency. Further, nothing contained in this MOU constitutes a mandate or a requirement imposed on FDA or CDC that is additional to the mandates or requirements imposed on them, individually or collectively, by federal statutes and regulations.

VI. TERMINATION AND MODIFICATION

This agreement, when accepted by FDA and CDC, may be modified or terminated by mutual written consent of the agencies or may be terminated by either agency upon a 60-day advance written notice to the other.

Footnotes

[1] Eligible medial countermeasures (MCMs) refer to eligible products, such as drugs, biological products (e.g., vaccines, blood products, end biological therapeutics), and devices (e.g., in vitro diagnostics and personal protective equipment), for use in emergencies involving chemical biological, radiological, or nuclear (CBRN) threats, as defined in section 564A(a) of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360bb3a).

[2] Public Law 113-5, 127 Stat 161 (March 13, 2013).

[3] HHS. HHS Delegation of Authority of section 564A(e) of the Federal, Food, Drug, and Cosmetic Act. December 16, 2013.

[4] Section 564A(e)(2) of the FD&C Act.

[5] The intended EUI must be for a product intended to be used to prevent, treat, or diagnose a disease or condition caused by a CBRN agent, or caused by a countermeasure for such an agent, when that agent is the subject of a determination of emergency made by the Secretary of Health and Human Services, Homeland Security, or Defense under section 564(b) (1) of the FD&C Act.

[6] For a copy of this MOU, see: MOU 225-14-0017 (/about-fda/domestic-mous/mou-225-14-0017).

[7] For a copy of this MOU, see: MOU 225-13-013 (/about-fda/domestic-mous/mou-225-13-013).

APPROVED AND ACCEPTED FOR
FOOD AND DRUG ADMINISTRATION

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February 22, 2016

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