

Management and Budget, Paperwork Reduction Project, Fax: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: February 11, 2008.

Janean Chambers,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA No. 225-08-8002]

Memorandum of Understanding Between the Division of Select Agents and Toxins Center for Disease Control and Prevention and the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Division of Select Agents and Toxins (DSAT) of the Centers for Disease Control and Prevention (CDC). The purpose of this MOU is to establish a procedure to allow CDC/DSAT to confirm that FDA has accepted or approved, under the authority of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq), an Investigational New Drug application (IND), a request to establish an Investigational New Animal Drug file (INAD), or an Investigational Device Exemption application (IDE) for a clinical trial involving the use of an investigational product that is, bears, or contains a select agent or toxin.

DATES: The agreement became effective January 25, 2008.

FOR FURTHER INFORMATION CONTACT:

Jarilyn Dupont, Director of Regulatory Policy, Office of Policy and Planning (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5906.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: February 8, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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Memorandum of Understanding
Between
The Division of Select Agents and Toxins
Centers for Disease Control and Prevention
And
Food and Drug Administration

PURPOSE

The purpose of this Memorandum of Understanding (MOU) is to establish a procedure to allow the Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC) to confirm that the Food and Drug Administration (FDA) has accepted or approved, under the authority of the Food, Drug, and Cosmetics Act (21 U.S.C. 301 *et seq.*), an Investigational New Drug application (IND), a request to establish an Investigational New Animal Drug file (INAD) or an Investigational Device Exemption application (IDE) for a clinical trial involving the use of an investigational product that is, bears, or contains a select agent or toxin.

DEFINITIONS

The terms "select agent or toxin" and "entity" have the same meaning as defined in 42 C.F.R. part 73.

BACKGROUND

Part 73 of Title 42, Code of Federal Regulations (Select Agent regulations), sets forth the requirements regarding the possession, use, or transfer of select agents and toxins. The regulations implement provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Select Agent regulations provide that an entity may not possess or use in the United States, receive from outside the United States, or transfer within the United States, any select agent or toxin unless the entity has been granted a certificate of registration by the Secretary of the Department of Health and Human Services (HHS), or the Secretary of Agriculture. However, the Select Agent regulations provide that the Secretary of HHS may exempt from those requirements, on a case by case basis and where additional regulation is not necessary to protect public health, an investigational product being used in an investigation authorized under: the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*); Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262); the Virus-Serum-Toxin Act (21 U.S.C. 151-159); or the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*). Under the implementing regulations for the Federal Food, Drug, and Cosmetic Act, FDA has the authority to accept or approve an Investigational New Drug application (IND), a request to establish an Investigational New Animal Drug file (INAD), or an Investigational Device Exemption application (IDE) if it meets the requirements of 21 CFR Part 312, 21 CFR Part 511 or 21 CFR Part 812 respectively. The DSAT desires to obtain confirmation from FDA regarding whether an IND, INAD or IDE has been accepted or approved in order to determine whether an investigational product that is, bears,

or contains a select agent or toxin is being used in a clinical investigation that has been authorized under the Federal Food, Drug and Cosmetic Act. This information will aid the DSAT in determining whether to approve an exemption of an investigational product that is, bears, or contains a select agent or toxin from the requirements of Part 73. The Select Agent regulations require that the DSAT make a determination regarding an application for an exemption within 14 calendar days after receipt.

PROCEDURES

The DSAT agrees to:

1. Designate in writing to FDA the name and contact information of the DSAT representative who will be responsible for requesting confirmation of FDA acceptance or approval of an IND, INAD, or IDE for an investigational product that is, bears, or contains a select agent or toxin being used in a clinical investigation.
2. Inform each sponsor of a clinical investigation for which it intends to confirm the existence of an IND, INAD or IDE, that as a condition of considering the sponsor's exemption request, the DSAT is going to confirm with FDA the existence and status of such IND, INAD or IDE;
3. Obtain from each sponsor requesting an exemption under the Select Agent regulations, a signed authorization allowing FDA to confirm to the DSAT the existence and status of the IND, INAD or IDE, and agreeing that such a confirmation will not violate FDA's information disclosure regulations, the Federal Food, Drug, and Cosmetic Act, or the Trade Secrets Act (18 U.S.C. § 1905).
4. Provide, either electronically or by facsimile, the following information and documents to FDA, when requesting confirmation of whether FDA has accepted or approved an IND, INAD or IDE for an investigational product that is, bears, or contains a select agent or toxin:
 - The IND, INAD or IDE number
 - The name of the sponsor requesting the exemption
 - The name of the select agent
 - The name of the product that is, bears, or contains a select agent
 - The date the IND, INAD, or IDE was submitted to FDA by the sponsor
 - The name of the FDA center (e.g. CBER; CDER; CDRH; or CVM) and name of the review office or division where the IND, INAD or IDE was submitted
 - The signed authorization referred to in paragraph 3, above.

5. Certify that the DSAT will use the information to be provided by FDA only for the purpose of determining whether to approve a request for exemption of the investigational product that is, bears, or contains a select agent or toxin from the requirements of 42 C.F.R. part 73, and that the DSAT will not further disclose the records or information without the written permission of the FDA, unless otherwise authorized by the sponsor.

FDA agrees to:

1. Designate in writing to the DSAT the name and contact information of the FDA representative(s) who will be responsible for providing confirmation of whether FDA has accepted or approved an IND, INAD or IDE for an investigational product that is, bears, or contains a select agent or toxin.
2. Confirm by email within 3 working days from the receipt of the information specified in paragraph 4 above, to the DSAT contact, whether FDA has accepted or approved an IND, INAD or IDE for an investigational product that is, bears, or contains a select agent or toxin, and confirm that the IND, INAD or IDE is not on hold, not withdrawn and/or still in effect at the time of the confirmation.
3. Upon request pertaining to a particular IND, INAD or IDE, notify the DSAT of whether any IND, INAD, or IDE for an investigational product that is, bears, or contains a select agent or toxin has been withdrawn, placed on hold or is otherwise not in effect.

This MOU supercedes any previous agreement between the DSAT at CDC and FDA or any component of FDA concerning information requested pursuant to the Select Agent regulations.

Contacts: For general information concerning this agreement.

A. For the Centers for Disease Control and Prevention

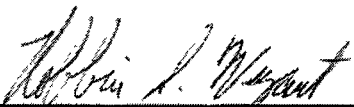
Lori J. Bane
Compliance Officer
CDC, Div. Of Select Agents and Toxins
(404) 718-2006
Zoz1@cdc.gov

B. For the Food and Drug Administration.

Jarilyn Dupont
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EFFECTIVE DATE

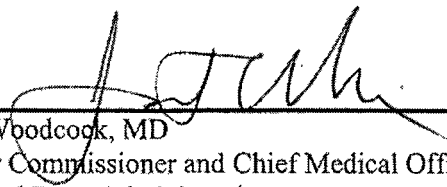
This MOU is effective as of the date when it has been signed by both parties, and may be amended at any time by mutual agreement of the DSAT, CDC and FDA. All amendments must be in writing and signed by the parties.



Robbin Weyant, PhD, CAPT, USPHS
Director, Division of Select Agents and Toxins
Centers for Disease Control and Prevention



Date



Janet Woodcock, MD
Deputy Commissioner and Chief Medical Officer
Food and Drug Administration



Date