

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA No. 225-08-8002]

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Certifier D. Hawkins

**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: 2/8/08
February 8, 2008.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[INSERT MOU]

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

