facilitating the use of a centralized IRB review process.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Nancy Stanisic, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1660, or

Steve Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration,1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210, or

David Lepay, Good Clinical Practice Program, Office of Science and Health Coordination (HF–34), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 28, 2005 (70 FR 15635), FDA published a notice announcing the availability of a draft guidance entitled ''Using a Centralized IRB Process in Multicenter Clinical Trials.'' The notice gave interested persons an opportunity to submit comments by May 27, 2005. The agency received only a small number of comments, and we carefully considered the received comments as we finalized the draft guidance. Other than minor editorial changes and some clarifications, no substantive changes were made to the draft guidance.

This guidance is intended to assist sponsors, institutions, IRBs, and clinical investigators involved in multicenter clinical research in meeting the requirements of 21 CFR part 56 by facilitating the use of a centralized IRB review process. The guidance does the following: (1) Describes the roles of the participants in a centralized IRB review process, (2) offers guidance on how a centralized IRB review process might consider the concerns and attitudes of the various communities participating in a multicenter clinical trial, (3) makes recommendations about documenting agreements between a central IRB and the IRBs at institutions involved in the centralized IRB review process concerning the responsibilities of a central IRB and each institution's IRB, and (4) discusses IRB procedures for implementing a centralized review process. Finally, the guidance recommends how to ensure effective IRB review for clinical trial sites not already affiliated with an IRB. This guidance applies to clinical investigations conducted under 21 CFR part 312 (investigational new drug application or IND regulations).

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance. Submit a single copy of electronic comments or two paper copies, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/cder/guidance/index.htm*. *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3785 Filed 3–15–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–06–8000]

Confidentiality Arrangement Between the United States Food and Drug Administration and the French Health Products Safety Agency

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a confidentiality arrangement between the United States Food and Drug Administration and the French Health Products Safety Agency. The purpose of this confidentiality arrangement is to establish mutual commitments to retain the confidentiality of non-public information shared between the agencies.

DATES: The agreement became effective February 8, 2006.

FOR FURTHER INFORMATION CONTACT: Matthew E. Eckel, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville MD, 20857, 301–827–4480, FAX: 301–480–0716.

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

Dated: March 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

CONFIDENTIALITY ARRANGEMENT

BETWEEN

THE UNITED STATES FOOD AND DRUG ADMINISTRATION

AND

THE FRENCH HEALTH PRODUCTS SAFETY AGENCY

The United States Food and Drug Administration (USFDA) and the French Health Products Safety Agency (Afssaps) (hereinafter the Participants) consider it to be a necessity to establish and maintain a high level of co-operation between USFDA and Afssaps in order to increase medical safety and the protection of public health. In order to attain that high level of co-operation, it is essential to be able to share information that is protected from public disclosure by French or U.S. law (non-public information) as part of cooperative law enforcement or regulatory activities.

Such non-public information includes documents held or prepared by the USFDA or Afssaps, whether final or pre-decisional, containing: 1) information the public disclosure of which would be likely to harm the personal privacy of an individual or the secrecy of personal files or would constitute a clearly unwarranted invasion of personal privacy, such as medical files; 2) trade secret information, including any commercially valuable plan, formula, "recipe," process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort, for example, information relating to the manufacturing process; 3) confidential commercial or financial information of a type that the submitter would customarily not release to the public or the disclosure of which would be likely to cause substantial harm to the competitive position of the submitter; 4) information compiled during or about an investigation for purposes of conducting any potential or actual enforcement activities; or 5) internal, pre-decisional information, for example opinions and recommendations that are part of agency deliberations. Such information may be in statistical, technical, legal, or operational form and shared either orally or in writing, whatever the medium used for the capture, storage, or transmission of the information.

Both Participants consider that such information is shared in confidence, consider it critical that the other maintains the confidentiality of such information, and recognize that public disclosure of this information could seriously jeopardize any further scientific and regulatory interactions between the Participants.

The Participants commit as follows:

1. The Participants have the authority to protect from public disclosure the above-mentioned non-public information without prejudice to the application of legal provisions currently in force under which the courts may order the Participants to release a given document. The Participants will ensure that such information that is received from the other Participant will only be made available to employees or contractors of the Participants who have a

need to know for the purpose of achieving the Participants' missions of medical safety and who are bound by an obligation to maintain the confidentiality of the information.

2. The Participants will not publicly disclose such non-public information without written authorization from the owner of the information, written authorization from the individual who is the subject of the personal privacy information, or a written statement from the other Participant that the information no longer has non-public status;

3. Each Participant will inform the other promptly of any effort made by judicial or legislative mandate to obtain non-public information received from the other Participant. If such judicial or legislative mandate orders disclosure of such non-public information, the Participant will take all appropriate legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure.

4. Each Participant will promptly inform the other of any changes to the Participant's laws, regulations, or any relevant policies or procedures that would affect the Participant's ability to honor the commitments in this document.

5. Requests for non-public information will be made in written form (mail, electronic mail, telefax. etc.) and the documents requested pursuant to this agreement will be supplied in language of the Participant supplying the information.

6. This agreement shall become effective on the date of the signature of both Participants and shall thereafter continue for 5 years, renewable upon mutual written consent.

Agreed and accepted on behalf of USFDA:

Andrew C. von Eschenbach, M.D. for

Acting Commissioner of Food and Drugs
Food and Drug Administration
Department of Health and Human Services
United States of America

Date: 31 Jan 06

Agreed and accepted on behalf of Afssaps:

Jean MARIMBERT

Directeur Général
Agence française de sécurité sanitaire des produits de santé (Afssaps)
FRANCE

Date: 08 Fe. 06

[FR Doc. 06–2539 Filed 3–15–06; 8:45 am]
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