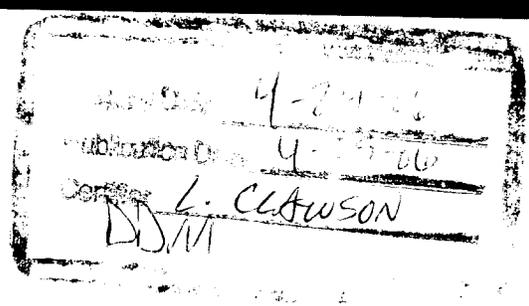


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0150]



Guidance for Sponsors, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable.” This guidance is intended to inform sponsors, institutional review boards, clinical investigators, and agency staff that under circumstances described in the guidance, that FDA does not intend to object to the use in device investigations, without informed consent, of leftover human specimens that are not individually identifiable. FDA intends to include in this policy leftover specimens that are remnants of specimens collected for routine clinical care or analysis that would otherwise have been discarded, specimens obtained from specimen repositories, and specimens that are leftover from specimens previously collected for other unrelated research. This guidance document will be implemented immediately, but it remains subject to comment in accordance with the agency’s good guidance practices (GGPs).

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DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-276-0496.

SUPPLEMENTARY INFORMATION:

I. Background

Under FDA's current regulations governing the conduct of *in vitro* diagnostic (IVD) studies, the definition of human subject includes human specimens (see 21 CFR 812.3(p)). Because these regulations require informed consent for all FDA-regulated human subject research, except in limited circumstances specified in FDA regulations, informed consent is required

before specimens can be used in FDA-regulated research (see 21 CFR part 50). This aspect of FDA's human subject protection regulations has created confusion and difficulty for persons developing IVDs. Many clinicians, research hospitals, and companies have viewed the requirement for informed consent for IVD studies using leftover specimens to be unnecessary to protect human subjects and to be overly burdensome and costly.

FDA has recently focused on unnecessary obstacles to medical product development. The agency has received comments from trade associations and research institutions that identify the challenge of obtaining informed consent for the use of leftover specimens as an unnecessary obstacle and expense to investigational efforts. When leftover specimens are available, it is often difficult, if not impossible, to locate the donor and obtain consent.

The confusion regarding the application of informed consent requirements to IVD studies and concerns about unnecessary obstacles to product development have prompted FDA to issue this guidance document. The agency believes that the policy expressed in this guidance will facilitate product development in a manner consistent with values of human subject protection.

FDA intends that the exercise of enforcement discretion expressed in this guidance document begin immediately. In accordance with FDA's GGP regulation (21 CFR 10.115), you may comment on this guidance at any time. The agency will consider your comments and determine whether to revise the guidance at a later date.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGP regulation. 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 statute and regulations.

III. Electronic Access

To receive "Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable" by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1588 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

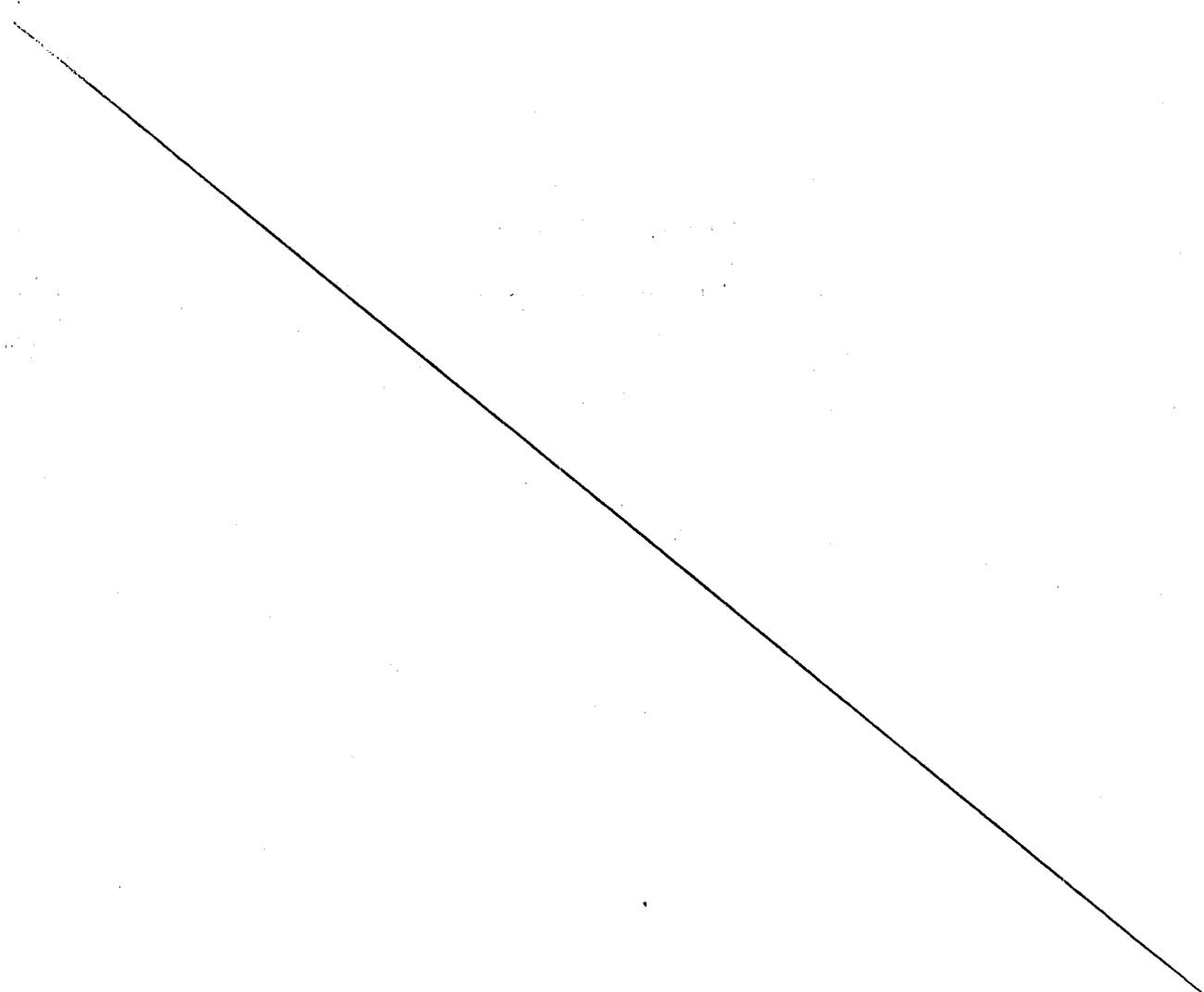
IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collection of

information in this guidance was approved under the emergency processing provisions of the PRA and was assigned OMB control number 0910-0582.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4/11/06
April 11, 2006



Jeffrey Shuren,
Assistant Commissioner for Policy

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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