DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Registration and Listing Grassroots Meeting for Medical Device Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: Registration and Listing Grassroots Meeting for Medical Device Manufacturers. The topic to be discussed is FDA's intention to propose changes to the current medical device registration and listing process. This meeting is being conducted to provide a forum in which FDA can obtain industry views on changes to the device registration and listing system that FDA is currently considering. The changes being considered are aimed at streamlining the collection of registration and listing data, improving the accuracy and quality of the data in the system, and decreasing the time it takes manufacturers to register their establishments and list their devices, while ultimately reducing FDA's cost of maintaining the registration and listing system.

DATES: The meeting will be held on July 15, 1999, 8:30 a.m. to 12 m.; registration will begin at 8 a.m.

ADDRESSES: The meeting will be held at the Holiday Inn Minneapolis West (Calhoun Ballroom), 9970 Wayzata Blvd., St. Louis Park, MN, 612–593–1918, FAX 612–593–0150.

FOR FURTHER INFORMATION CONTACT: Bryan H. Benesch, Office of Health and Industry Programs (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 ext. 131, e-mail ''BHB@CDRH.FDA.GOV''.

For registration information: Rhonda L. Mecl, Supervisory Investigator, Minneapolis District Office, Food and Drug Administration, 240 Hennepin Ave., Minneapolis, MN 55401–1912, FAX 612–334–4134.

Those persons interested in attending the meeting should fax their registration including name, title, firm name, address, telephone, and fax number. There is no charge to attend this meeting, but advance registration is requested due to limited seating. If you need special accommodations due to a disability, please contact Rhonda L. Mecl at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Over the past one and a half years, FDA has reviewed the entire registration and listing process to determine if the process can be made more efficient and accurate. This was one of many reengineering efforts conducted by the Center for Devices and Radiological Health (CDRH). This reengineering effort has resulted in a number of suggestions aimed at improving the registration and listing process for both FDA and industry. This meeting will help FDA obtain the medical device industry perspective on the changes under consideration and suggestions for additional changes. FDA has held three meetings on the same subject on April 20 and 21, 1999, in California (64 FR 12813, March 15, 1999) and on May 25, 1999, in Rockville, MD (64 FR 20006, April 23, 1999).

Some of the changes that FDA is currently considering include the following:

(1) Require industry submission of registration and listing information through the World Wide Web (WEB). What are the advantages and disadvantages to industry and how would industry be affected if WEB submissions were mandated?

(2) Require that owners and parent companies register and list and take responsibility for the registration and listing of their establishments. What is the highest level in a company that should be responsible for registration and listing and how should this level be defined/described?

(3) Require that additional data elements be submitted to FDA, e.g., premarket submission numbers for those devices that have gone through the premarket notification (510(k)), premarket approval, or product development protocol process.

(4) Because of the ease of submission through the WEB, require that firms register and list within 5 days (current requirement is 30 days) of entering into an operation that requires registration and listing.

A summary report of the meeting will be available on CDRH's Registration and Listing Process Reengineering Team website approximately 20 working days after the meeting. The CDRH Registration and Listing Process Reengineering Team home page may be accessed at ''http://www.fda.gov/cdrh/grassroots/reglist.htm''.

Dated: June 13, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–15756 Filed 6–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1878]

''Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV);'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance (dated June 1999) entitled ''Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV).'' The draft guidance is intended to provide recommendations for donor screening and supplemental testing for antibody to HCV, and notification of consignees and quarantine of prior collections from a donor who later tests repeatedly reactive for antibody to HCV (including single antigen and multiantigen screening tests), notification of consignees and recipients of blood and blood components at increased risk for transmitting HCV. The draft guidance, when final, is intended to supersede the September 1998 guidance entitled ''Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV.''

DATES: Written comments on the draft guidance may be submitted at any time, however, comments should be submitted by August 23, 1999, to ensure their adequate consideration in preparation of the final document. Submit written comments on the

information collection provisions by August 23, 1999.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Test for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV)'' to 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. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

For technical/scientific questions, contact Robin M. Biswas, Center for Biologics Evaluation and Research (HFM–325), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3011, or FAX 301–496–0338.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance (dated June 1999) entitled ''Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Test for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV).'' The draft guidance is intended to provide recommendations for appropriate action when a repeat donor subsequently tests repeatedly reactive for HCV using either a single antigen or multiantigen screening test, commonly referred to as HCV ''lookback.'' The draft guidance provides recommendations for the following: (1) Quarantine (and disposition of products) of prior collections from donors who later test repeatedly reactive for anti-HCV using either a single antigen or multiantigen screening test, (2) supplemental testing and notification of consignees and transfusion recipients, (3) procedures and recordkeeping, (4) review of records of donor testing for ''historical'' repeatedly reactive donations, and (5) additional testing of donors with no record of supplemental testing on the ''historical'' repeatedly reactive screening test or with an indeterminate recombinant immunoblot assay 2.0 test result.

On March 20, 1998 (63 FR 13675), FDA announced the availability of ''Guidance for Industry: Supplemental Testing and the Notification of Consignees of Test Results for Antibody to Hepatitis C Virus (Anti-HCV),'' (the March 1998 guidance). The March 1998 guidance superseded the recommendations related to HCV in FDA's July 19, 1996, guidance entitled: ''Recommendations for Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human T–Lymphotropic Virus Type I (HTLV–I)'' (the July 1996 guidance). The March 1998 guidance did not, however, supersede the recommendations related to HTLV and HBV in the July 1996 guidance. (Note: The scope of the July 1996 guidance was limited to enzyme immunoassay (EIA) 2.0 and 3.0 screening performed since 1992.)

On June 18, 1998, at a public meeting of its Blood Products Advisory Committee (BPAC), FDA announced plans to respond to public comments submitted to the docket for the March 1998 guidance by issuance of a comprehensive guidance. At the BPAC meeting, FDA announced it was considering changes to the HCV ''lookback'' policy based on considerations which had been raised by public comments. FDA continued to receive extensive public comments to the docket which were evaluated carefully by CBER. Under the agency's good guidance practices, FDA issued a notice on September 8, 1998, to withdraw the March 1998 guidance pending issuance of a second comprehensive guidance.

In September 1998, FDA finalized a guidance entitled ''Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV'' (the September 1998 guidance). The September 1998 guidance superseded the March 1998 guidance. FDA announced the availability of this document in the **Federal Register** of October 21, 1998 (63 FR 56198).

On January 28, 1999, the Public Health Service Advisory Committee on Blood Safety and Availability (The PHS Advisory Committee) met to consider whether to expand the targeted HCV ''lookback'' program to include recipients of blood from donors subsequently identified as repeatedly reactive by the single antigen EIA 1.0 screening test for HCV infection that was licensed in 1990. Approximately 80 percent of the EIA 1.0 repeatedly reactive donations occurred before the first supplemental test became available. The PHS Advisory Committee concluded that, for EIA 1.0 repeatedly reactive donations without supplemental testing, it would be reasonable to limit the ''lookback'' based on the signal to cutoff value of the screening test in cases where supplemental testing had not been done. The PHS Advisory Committee concluded that it would be optimal to perform HCV ''lookback'' on a subset of the donors testing repeatedly reactive on EIA 1.0 screening tests to capture the vast majority of the true positives and minimize the unnecessary false recipient notifications.

This draft guidance represents the agency's current thinking on the management of prior collections from donors testing repeatedly reactive at a later date using a single antigen or multiantigen screening test for antibody to HCV, including product quarantine, further testing of the donor, and notification of consignees and transfusion recipients. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not

intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV).

This draft guidance recommends that blood establishments prepare and follow written procedures when blood establishments have collected Whole Blood, blood components, Source Plasma, and Source Leukocytes later determined to be at risk for transmitting HCV infections. This draft guidance provides recommendations, similar to the requirements now in effect for HIV ''lookback'' (21 CFR 610.46 and 610.47 reported and approved under OMB Control No. 0910–0336), to clarify the status of the donor who later tests repeatedly reactive for HCV, to quarantine prior collections from such donors, and to notify consignees and transfusion recipients, as appropriate, based on further testing of the donor. The draft guidance recommends that when a donor who previously donated blood is tested in accordance with this draft guidance on a later donation, and tests repeatedly reactive for antibody to HCV, the blood establishment should perform an additional test using a licensed test, and notify consignees who received Whole Blood, blood components, Source Plasma, and Source Leukocytes from prior collections so that appropriate action is taken. The draft guidance document recommends that blood establishments and consignees quarantine previously collected Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors, and if appropriate, consignees should notify transfusion recipients. In addition to these ''lookback'' recommendations, which are similar to the ''lookback'' requirements for HIV, this draft guidance recommends a retrospective review of testing records dating back indefinitely to the extent that electronic or other readily retrievable records are available, to indentify collections from donors who had tested repeatedly reactive in the past, prior to the existence of guidance recommending ''lookback'' activities. However, the recommendations provide for the review of records to be limited to a lesser period of time, that is, 12 months prior to the last negative licensed multiantigen screening test, whenever there is a record of such a prior test. The draft guidance recommends that blood establishments notify consignees of the risk of HCV transmission that exists for prior collections based on the retrospective review of records and the results of the additional testing performed before or as a result of the retrospective review of records. In addition, the draft guidance recommends that blood establishments notify consignees of the risk of HCV transmission that exists for prior collections from a donor who tested repeatedly reactive on a screening test for HCV and for whom the blood establishment has no record of further testing and the repeatedly reactive results cannot be clarified because further testing is impractical or infeasible. This draft guidance recommends that blood establishments maintain records of the source and disposition of all units of blood and blood products for at least 10 years from the date of disposition or 6 months after the latest product expiration date, whichever is the later date. Under 21 CFR 606.160 (reported and approved under OMB Control No. 0910–0116), such records are required to be retained for 5 years. FDA is recommending an extended records retention period because advances in medical diagnosis and therapy have created opportunities for disease prevention or treatment many years after recipient exposure to a donor later determined to be at increased risk for transfusion-transmitted disease. Additionally, methods of recordkeeping have advanced, improving the ability of blood establishments to more easily maintain and retrieve records. Also, this draft guidance recommends that any consignee of a blood establishment notify the transfusion recipients or their physicians of blood and blood components at increased risk for transmitting HCV. The agency is issuing this draft guidance to promote the continued safety of the blood supply, to help provide users with critical information about blood and blood components, and to promote notification to transfusion recipients who have received blood and blood components at risk for transmitting HCV so that recipients may receive medical counseling.

Respondents to this information collection are blood establishments (business and not-for-profit) and consignees of blood establishments, including hospitals, transfusion services, and physicians. The total

reporting and recordkeeping burden is estimated to be 723,508 hours. However, of this total, approximately 715,986 hours would be expended on a one-time basis for establishing the written procedures and doing the one-time retrospective review of records. Therefore, 8,242 hours is estimated as the ongoing annual burden related to this draft guidance. The total ongoing prospective annual burden for blood establishments is estimated to be 2,880 hours. The prospective annual burden for consignees of blood establishments is estimated to be 5,362 hours.

Based on the June 1998 registration records, there are approximately 2,800 FDA registered blood collection facilities in the United States that collect approximately 27 million units of whole blood and source plasma annually of which, based on the Centers for Disease Control and Prevention (CDC) estimates, there are approximately 9,750,000 donations from repeat donors per year. Based on the prevalence of HCV among donors from 1996 to 1998, CDC estimates that 7,200 of those repeat donors per year would test repeatedly reactive for HCV. For each of these donors, the recommendations in this draft guidance call for blood establishments to notify the consignee (transfusion service) two times, once for quarantine purposes and again with additional test results for a total of 14,400 notifications as an annual ongoing burden. Based on estimates from CDC, FDA expects that for the one-time review of records, as many as 1,117,000 blood products would be at increased risk for transmitting HCV. For each of these products, blood establishments would notify consignees to quarantine these products, report additional test results to consignees, and consignees would notify recipients or recipients' attending physicians. In March 1999, CDC estimated that there could be approximately 566,000 recipients that should be notified after a retrospective review of donor records between May 1990 and June 1998. FDA estimates that a total of 2,234,000 notifications, 1,117,000 affected blood products times 2 notifications, would result from the retrospective review. The total annual responses for blood establishments is estimated to be the combined number of notifications, prospective and retrospective, or 2,248,400. FDA estimates the amount of time for each notification of a consignee by a blood establishment will be approximately 6 minutes (0.1 hours). Consequently, the total estimated reporting burden hours for blood establishments is 224,840 hours. However, the ongoing annual burden not associated with the retrospective review would be 1,440 hours, 14,400 prospective notifications times 0.1 hour per notification.

CDC expects that approximately 2,232 repeat donors who have repeatedly reactive HCV screening test results will confirm positive for HCV each year. Based on CDC's research and information, a donor who confirms positive for HCV will have donated on the average only two previous times and on the average two components will have been made from each donation. Based on this information, there could be 8,936 transfusion recipients that should be notified per year. The total notifications by consignees is estimated to be 574,936 annually, 566,000 recipients notified due to the retrospective review plus 8,936 recipients due to the prospective review. The time estimated for consignees to make a notification is 30 minutes or 0.5 hours on average. This time allows for the possibility of a consignee having to make up to 3 attempts to complete the notification process and creates a total reporting burden of 287,468 hours. According to the Health Care Financing Administration, there are approximately 6,200 consignees that should be responsible for notification.

In Table 2 of this document, the 40 hours per blood establishment recordkeeper represents the time to develop written procedures for the HCV ''lookback'' recommendations and to update an estimated 4 HCV repeat reactive records as an ongoing annual burden. FDA estimates that it takes approximately 5 minutes to update each record. Therefore, the total recordkeeping by blood establishments is estimated to be 112,000 hours 2,800 registered blood establishments times 40 hours per establishment. FDA estimates that each consignee recordkeeper would need 16 hours to develop written procedures for the HCV ''lookback'' notification process and to update approximately 1 to 2 transfusion recipient records. FDA estimates that it takes approximately 5 minutes to update each record. Therefore, the total recordkeeping burden for consignees is estimated to be 99,200 hours. The combined total recordkeeping burden for both blood establishments and consignees is estimated to be 211,200 hours. However, based on the prospective number of repeat donors per year and the number that confirm positive for HCV, the ongoing annual recordkeeping burden may only be 2,334 hours. Over time, we expect the ongoing annual recordkeeping burden to decline as the prevalence of HCV among donors has declined due to the implementation of screening tests for anti-HCV, which helps to reduce the number of persons infected with HCV from the donor pool.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Collection Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Blood Establishments	2,800	803	2,248,400	0.1	224,840
Consignees	6,200	93	574,936	0.5	287,468
Total					512,308

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Collection Activity	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Total Hours
Blood Establishments	2,800	5	10,000	40	112,000
Consignees	6,200	2.5	15,136	16	99,200
Total					211,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Maintenance costs were not estimated for the additional maintenance of records beyond the current 5 years to the recommended 10 years because modern storage technology has markedly reduced the space needed to store records.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this draft guidance to OMB for review. Interested persons may submit comments regarding this information collection by August 23, 1999, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

IV. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: June 16, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–15754 Filed 6–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1737]

Public Availability of Information on Clinical Trials for Investigational Devices Intended to Treat Serious or Life-Threatening Conditions; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Devices and Radiological Health, is requesting comments concerning the feasibility of including information for device investigations for serious or life-threatening diseases and conditions in a public data bank. This action is being taken to assist the agency in preparing a report to Congress required under the FDA Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is announcing an open public meeting on this subject.

DATES: Written comments by August 23, 1999.

ADDRESSES: Written comments concerning this document must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert R. Gatling, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190, ext. 140 or e-mail ''rrg@cdrh.fda.gov''.

SUPPLEMENTARY INFORMATION: FDAMA (Pub. L. 105–115) was enacted on November 21, 1997. Section 113(a) of FDAMA amends section 402 of the Public Health Service Act (PHS Act) (42 U.S.C. 282) by adding a new section 402(j). This new section directs the Secretary of Health and Human Services (the Secretary), acting through the Director of the National Institutes of Health (NIH), to establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions.

Section 113(b) of FDAMA (collaboration and report) directs the Secretary, the Director of NIH, and the Commissioner of Food and Drugs to collaborate to determine the feasibility of including device investigations within the scope of the data bank under new section 402(j) of the PHS Act. In addition, section 113(b) of FDAMA directs the Secretary to prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report on the following:

1. The public health need, if any, for inclusion of device investigations within the scope of the data bank under section 402(j) of the PHS Act;

2. The adverse impact, if any, on device innovation and research in the United States if information relating to such device investigations is required to be publicly disclosed; and,

3. Such other issues relating to section 402(j) of the PHS Act as the Secretary determines to be appropriate.

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) permits the investigational use of devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices. Part 812 (21 CFR part 812) contains the implementing regulations for section 520(g) of the act. In accordance with part 812 and the agency's public information regulations, FDA generally will not disclose the existence of an investigational device exemptions (IDE) application unless its existence has previously been publicly disclosed or acknowledged, until FDA approves an application for premarket approval (PMA) for the device, or until a notice of completion of a product development protocol (PDP) for the device has become effective. The establishment of a data bank intended to contain publicly available information about certain IDE's would require changes in these implementing regulations. Section 113(b) of FDAMA requires the Secretary to evaluate whether public disclosure of IDE information would adversely impact device innovation and research.

The provisions of section 113 of FDAMA apply to drugs for ''serious or life-threatening diseases and conditions.'' Any consideration of inclusion of device trials within the scope of the data bank requires a definition of what types of devices would be covered. FDA does not currently have a definition for ''serious'' or ''life-threatening,'' as those terms would apply to devices.

In the **Federal Register** of September 18, 1997 (62 FR 48940), FDA published a final rule for treatment use of an investigational device. The rule added § 812.36 (21 CFR 812.36). In the preamble to the final rule, FDA explained that it did not define ''serious disease or condition'' because the agency concluded that defining the term