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section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this draft guidance to OMB for review.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

could be unduly restrictive and limit the agency's discretion when determining whether certain stages of a disease or condition are ''serious.'' Instead, § 812.36(a) applies the treatment IDE rule to ''immediately life-threatening'' diseases, and defines that as a stage of a disease in which there is a reasonable likelihood that death would occur within a matter of months or in which premature death is likely without early treatment.

This definition could be used to help define the category of device trials that could be included in a clinical trials data bank. The clinical trials data bank could contain a list of clinical trials, whether Federally or privately funded, of investigational devices for serious or life-threatening diseases, a description of the investigational device, eligibility criteria for patients, the location of clinical trials sites, and a point of contact for those wanting to enroll in the trial. In evaluating the public health need for a device trials data bank and the effects a mandatory public data bank would have on innovation and research, FDA is currently assuming the devices that would fall within the scope of the provision are those intended to treat such ''immediately life-threatening'' situations, but FDA invites public comment on this issue.

FDA is in the process of consulting with NIH on the feasibility of adding device trials to the data bank. In addition, through this notice, FDA is soliciting comments and information that will help the agency draft its report to Congress under section 113(b) of FDAMA. In particular, FDA seeks input in response to the following questions:

1. Is there a public health need for inclusion of device investigations within the scope of the data bank under 402(j) of the PHS Act?

2. If there is a public health need, what category of device trials should be made publicly available and how should this category be defined? FDA's treatment IDE regulation applies only to devices for which no comparable or satisfactory alternative exists. Should a data bank for IDE's be similarly restricted? Should the trials that become part of the data bank include feasibility/pilot trials or only studies that are intended to demonstrate reasonable assurance of safety and effectiveness?

3. Investigational device trials have historically been smaller in numbers of subjects and numbers of investigational sites than investigational drug trials. What impact, both positive and negative, would the release of information have on these device trials, the sponsors, the investigators, the investigational sites, and the patients? Will a public data bank create pressures to increase the size of device trials or number of sites in situations where such expansion may increase risk to patients?

4. IDE information is generally protected from public disclosure under FDA regulations. If public disclosure were voluntary, would disclosure by one sponsor put pressure on sponsors of similar investigations to disclose the existence of their studies against their better judgment? Is this in the interest of the public health?

5. If disclosure is mandatory, is it likely to hamper innovations and investment in research and development? Would disclosure of these investigational device trials help or hinder research by increasing patient enrollment?

6. Because sponsors can recover some of the costs of the device research and development under the investigational device regulations, should FDA be concerned that publicly available information concerning investigational device trials will result in undue financial pressure or incentives on the trial sponsors to add subjects to the trials without appropriate consideration of risk? Should FDA be concerned about the possibility that improper promotion and commercialization will occur as a result of a public data bank for IDE trials?

7. Will public disclosure of information about device trials for products to treat serious or life-threatening diseases or conditions affect reimbursement policies of third party payers?

8. What other important information or issues should the agency consider?

FDA is planning a public meeting to give interested parties a chance to present their views on the feasibility, utility, and effects of a data bank for device trials. Information regarding the date and place of this meeting is published elsewhere in this issue of the **Federal Register**.

Interested persons may, on or before August 23, 1999Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 14, 1999.

Linda S. Kahan,

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

[FR Doc. 99–15757 Filed 6–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1081–2N]

Medicare Program; Cancellation of the June 24, 1999, Meeting of the Competitive Pricing Advisory Committee and the Area Advisory Committee for the Kansas City Metropolitan Area

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting cancellation.

SUMMARY: This notice announces the cancellation of the June 24, 1999, meeting of the Competitive Pricing Advisory Committee and the Area Advisory Committee for the Kansas City metropolitan area.

FOR FURTHER INFORMATION CONTACT: Sharon Arnold, Ph.D., Executive Director, Competitive Pricing Advisory Committee, Health Care Financing Administration, 7500 Security Boulevard C4–14–17, Baltimore, MD 21244–1850, (410) 786–6451 (for information about the CPAC).

Richard P. Brummel, Deputy Regional Administrator, Health Care Financing Administration, Richard Bolling Federal Building, Room 235, 601 East 12th Street, Kansas City, MO 64106, (816) 426–5233 (for information about the Kansas City metropolitan area AAC).

SUPPLEMENTARY INFORMATION: This notice announces the cancellation of the June 24, 1999, meeting of the Competitive Pricing Advisory Committee and the Area Advisory Committee for the Kansas City metropolitan area. The meeting will be rescheduled and announced in a subsequent **Federal Register** notice. (Section 4012 of the Balanced Budget Act of 1997, Pub. L. 105–33 (42 U.S.C.1395w–23 note) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App.2, section 10(a))

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)