The estimation of burden under section 113(a) reflects the relative inefficiency of this process for these firms.

Based on its experience reviewing INDs, consideration of the information in the previous paragraphs, and further consultation with sponsors who submit protocol information to the Clinical Trials Data Bank, FDA estimated that approximately 4.6 hours on average would be needed per response. The estimate incorporates 2.6 hours for data extraction and 2.0 hours for reformatting based on data collected from organizations currently submitting protocols to the Clinical Trials Data Bank. We considered quality control issues when developing the current burden estimates of 2.6 hours for data extraction and the 2.0 hours estimated for reformatting. Additionally, the Internet-based data entry system developed by NIH incorporates features that further decrease the sponsor's time requirements for quality control procedures. The Clinical Trials Data Bank was set up to receive protocol information transmitted electronically by sponsors. Approximately 10 percent of sponsors electronically transmit information to the Clinical Trials Data Bank. If the sponsor chooses to manually enter the protocol information, the data entry system allows it to be entered in a uniform and efficient manner primarily through pulldown menus. As sponsors' familiarity with the data entry system increases, the hourly burden will continue to decrease.

A sponsor of a study subject to the requirements of section 113 of the Modernization Act will have the option of submitting data under that section or certifying to the Secretary that disclosure of information for a specific protocol would substantially interfere with the timely enrollment of subjects in the clinical investigation. FDA has no means to accurately predict the proportion of protocols subject to the requirements of section 113 of the Modernization Act that will be subject to a certification submission. To date, no certifications have been received. It is anticipated that the burden associated with such certification will be comparable to that associated with submission of data regarding a protocol. Therefore, the overall burden is anticipated to be the same, regardless of whether the sponsor chooses data submission or certification for nonsubmission. Table 1 of this document reflects the estimate of this total burden.

In the **Federal Register** of May 14, 2007 (72 FR 27140), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

New Protocols	Recruitment Complete	Protocol Changes	New Investigators	Sites Closed	Total Responses	Hours Per Response	Total Hours
CDER (mandatory)	1,620	1,620	2,507	3,725	13,197	4.6	60,706
CBER (mandatory)	158	158	282	176	950	4.6	4,370
CDER (voluntary)	3,238	3,238	5,090	7,562	26,690	4.6	122,774
CDER (voluntary)	316	316	573	356	1,917	4.6	8,818
Total							196,668

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

CMS Burden Estimate:

The burden associated with CMS' requirements is the time and effort necessary for the provider to extract the data elements from the study protocol and reformatting and entering the information into the data bank. We estimate that approximately 745 clinical research studies will register on the NLM data bank. The number was derived from a search of the database on September 1, 2006, restricting the search by age (e.g., > 65 years of age); sponsor (e.g., NIH, industry, other federal agency, university/organization); Phase II, III, or IV; and by type of study (e.g., cancers and other neoplasms, diagnosis, and devices). The age, sponsor, and study phase was applied to each of the three separate searches by type of study. The following number of studies by study type, including trials no longer recruiting was 562 for diagnosis, 164 for cancers and other neoplasms, and 19 for devices. In determining the total number of hours requested, the CMS estimate uses the same assumptions used by FDA to estimate its total number of burden hours. Therefore, the total annual burden associated with this requirement is 27,480 hours (5,974 responses x 4.6 hours per response).

We believe the combined estimate of burden attributable to FDA and CMS requirements, 224,148 burden hours (196,668 burden hours + 27,480 burden hours) accurately reflects the total burden associated with this information collection request. We recognize that companies who are less familiar with the data entry system and the Clinical Trials Data Bank will require greater than 4.6 hours per response. However, as sponsor familiarity with the system increases, the hourly estimate will decrease.

Dated: October 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–20662 Filed 10–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0327]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Remote Medication Management System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Remote Medication Management System.'' This guidance document describes a means by which remote medication management systems may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal**

Register, FDA is publishing a final rule to classify remote medication management systems into class II (special controls). This guidance document is being immediately implemented as the special control for remote medication management systems, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on the 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 ''Class II Special Controls Guidance Document: Remote Medication Management System'' 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 240–276–3151. 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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Richard Chapman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2585.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying remote medication management systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for remote medication management systems. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the time frames established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the agency's current thinking on remote medication management systems. 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 ''Class II Special Controls Guidance Document: Remote Medication Management System,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1621 to identify the guidance you are requesting.

Persons interested in obtaining a copy of the guidance may 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 refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

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: October 3, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–20635 Filed 10–18–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0365]

Draft Guidance for Industry on the Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the