Trans #	Acquiring	Acquired	Entities
TRANSACTIONS GRANTED EARLY TERMINATION—06/06/2001			
20011790	The Bank of New York Company, Inc ...	The Charles Schwab Corporation	U.S. Trust Company of Florida Savings Bank U.S. Trust Company, National Association United States Trust Company of New York
20011868	SIG Holding AG	CIR-Compagnie Industriali Riunite S.p.A	Sasib S.p.A.
20011891	Parker Hannifin Corporation	Dana Corporation	Dana Corporation
20011896	Kerr-McGee Corporation	HS Resources, Inc	HS Resources, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—06/07/2001			
20011859	Tyco International, Ltd	Novartis AG	Novartis Corporation
20011907	Mizuho Holdings, Inc	Fifth Third Bancorp	Fifth Third Bancorp

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, contact representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary

[FR Doc. 01–16933 Filed 7–5–01; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0266]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for medical device registration and listing.

DATES: Submit written or electronic comments on the collection of information by September 4, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under 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, including each proposed extension of an existing 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.

Medical Device Registration and Listing—21 CFR 807.22 and 807.31 (OMB Control No. 0910–0387)—Extension

Section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) requires that manufacturers and initial importers engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and in commercial distribution register their establishments and list the devices they manufacture with FDA. This is accomplished by completing FDA Form 2891 entitled ''Initial Registration of Device Establishment'' and FDA Form 2892 entitled ''Medical Device Listing.'' In addition, each year active, registered establishments must notify FDA of changes to the current registration and device listing for the establishment. Annual changes to current registration information are preprinted on FDA Form 2891a and sent to registered establishments. The form must be sent back to FDA's Center for Devices and Radiological Health, even if no changes have occurred. Changes to listing information are submitted on Form 2892. On August 14, 2001, all hospitals who reprocess single-use devices will be required to register and list their activities. Under the Food and Drug Administration Modernization Act of 1997, foreign manufacturers are now required to register their establishments

and list their devices, but foreign registration and listing will be covered under a separate information requirement. FDA will also accept voluntary registration and listings from firms not covered above that wish to be registered with FDA.

In addition, under § 807.31 (21 CFR 807.31), each owner or operator is required to maintain a historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing. The owner or operator must maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing, but may discard labeling and advertisements from the file 3 years after the date of the last shipment of a discontinued device by an owner or operator. Along with the recordkeeping requirements above, the owner or operator must be prepared to submit to FDA all labeling and advertising mentioned above (§ 807.31(e)).

The information collected through these provisions is used by FDA to identify firms subject to FDA's regulations and is used to identify geographic distribution in order to effectively allocate FDA's field resources for these inspections and to identify the class of the device that determines the inspection frequency. When complications occur with a particular device or component, manufacturers of similar or related devices can be easily identified.

The likely respondents to this information collection will be domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution.

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

TABLE 1.—ESTIMATED YEAR 1 ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.22(a)	Form 2891 Initial Establishment Registration	2,045	1	2,045	0.25	511
807.22(a) (hospital reuse manufacturers)	Form 2891 Initial Establishment Registration	2,000	1	2,000	0.25	500
807.22(b)	Form 2892 Device Listing—initial and updates	3,450	1	3,450	0.50	1,725
807.22(b) (hospital reuse manufacturers)	Form 2892 Device Listing—initial and updates	2,000	10	20,000	0.50	10,000
807.22(a)	Form 2891(a)—Registration Update	16,500	1	16,500	0.25	4,125
807.31(e)		200	1	200	0.50	100
Total year 1 burden hours						16,961

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

TABLE 2.—ESTIMATED SUBSEQUENT YEARS ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.22(a)	Form 2891 Initial Establishment Registration	2,245	1	2,245	0.25	561
807.22(b)	Form 2892 Device Listing—initial and updates	3,650	1	3,650	0.50	1,825
807.22(a)	Form 2891(a)—Registration Update	18,500	1	18,500	0.25	4,625
807.31(e)		200	1	200	0.50	100
Total year 2 and year 3 burden hours						7,111

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

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
807.31	9,900	10	99,000	0.50	49,500
Total burden hours					49,500

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

This year's submission has broken out annual costs into two distinct phases, and the tables above summarized the estimated annual reporting burden hours for medical device establishments to report in compliance with the provisions imposed by this regulation.

Hospital Reprocessing of Single-Use Medical Devices

On August 14, 2001, hospitals who reprocess single-use devices will be

required to register their establishments and list those devices they reprocess. FDA has estimated that there will be approximately 2,000 such establishments that will fall into this category. The first year of the requirement will cause a one-time bolus of information to be submitted. FDA has separated the burden estimates into two tables to indicate year 1 (table 1 of this document) and subsequent year's estimates (table 2 of this document). Year 1 will include burden hours based on this bolus of submissions during the first year and subsequent year's estimates will indicate an adjustment for the new registrants for year 2 and beyond.

Burden Hour Explanation

The annual reporting burden hours to respondents for registering establishments and listing devices is estimated to be 16,961 hours, and recordkeeping burden hours for respondents is estimated to be 49,500 hours. The estimates cited in the tables above are based primarily upon the annual FDA accomplishment report, which includes actual FDA registration and listing figures from fiscal year (FY) 2000. These estimates are also based on FDA estimates of FY 00 data from current systems, conversations with industry and trade association representatives, and from internal review of the documents referred to in the previous tables.

According to 21 CFR part 807, all owners/operators are required to list, and establishments are required to register. Each owner/operator has an average of two establishments, according to statistics gathered from FDA's registration and listing database. The database has 16,500 active establishments listed in it. Based on past experience, the agency anticipates that approximately 4,045 registrations will be processed during the first year (because of hospitals who reprocess single-use), and 2,045 registrations thereafter. The agency also anticipates that approximately 5,450 initial and update device listings will be submitted the first year (due to hospitals who reprocess single-use devices), and 3,450 thereafter. FDA anticipates reviewing 200 historical files annually. Finally, because initial importers (currently estimated at 6,200) do not have to maintain historical files and because of the addition of 2,000 hospitals who reprocess single-use medical devices, FDA estimates that the number of recordkeepers required to maintain the initial historical information will be 9,900.

Dated: June 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–16987 Filed 7–5–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0277]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for reports of corrections and removals.

DATES: Submit written or electronic comments on the collection of information by September 4, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under 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, including each proposed extension of an existing 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.

Reports of Corrections and Removals—21 CFR Part 806 (OMB Control No. 0910–0359)—Extension

Section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)) directs FDA to issue regulations to require device manufacturers and importers to report promptly to FDA, any correction or removal of a device undertaken by such manufacturers and importers, if the correction or removal was undertaken to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. Under 21 CFR 806.10 and 806.20(a), FDA requires that each device manufacturer and importer shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health within 10-working days of initiating such correction or removal. In addition, each manufacturer and importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA, shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed