TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record-keeping	Total Annual Hours	Hours per Record	Total Hours
820.180(b) and (c)	8,963	1	8,963	1.50	13,445
820.181(a) through (e)	8,963	1	8,963	1.21	10,845
820.184(a) through (f)	8,963	1	8,963	1.41	12,638
820.186	8,963	1	8,963	0.40	3,585
820.198(a) through (c)	8,963	1	8,963	4.94	44,277
820.200(a) and (d)	8,963	1	8,963	2.61	23,393
820.25	8,963	1	8,963	0.67	6,005
Totals					3,072,337

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

Burden (labor) hour and cost estimates were originally developed under FDA contract by Eastern Research Group, Inc. (ERG), in 1996 when the CGMP/QS regulation became final. These figures are still accurate. Additional factors considered in deriving estimates included the following:

• Establishment Type: Query has been made of CDRH's registration/listing databank and has counted 8,963 domestic firms subject to CGMPs. In addition, hospitals that reuse or remanufacture devices are now considered manufacturers under new FDA guidance. After investigations of many hospitals and the changes in enforcements of FDA's requirements for hospitals, the number of reuse or remanufactures of single-use medical devices have decreased from the estimated 66 to an estimated 18 hospitals. Because the total number of registered firms is not static, the number of respondents will fluctuate from year to year resulting in slight changes to the overall burden. Currently, there are 8,963 firms subject to the CGMPs; an increase from the last renewal of 8,254.

• Potentially Affected Establishments: Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to FDA's quality policy regulations (§ 820.20(a)), document control regulations (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to FDA's design controls regulations (§ 820.30). The type of firm subject to each requirement was identified by ERG.

FDA estimates the burden hours (and costs) based on the last approved renewal for this information collection.

FDA estimates that some 650 ''new'' establishments (marketing devices for the first time) will expend some 143,052 ''development'' hours on a one-time startup basis to develop records and procedures for the CGMP/QS regulation.

FDA estimates that annual labor hours are apportioned as follows: (1) 40 percent goes to requirements dealing with manufacturing specifications, process controls, and the DHR; (2) 20 percent goes to requirements dealing with components and acceptance activities; (3) 25 percent goes to requirements dealing with equipment, records (the DMR and QSR), complaint investigations, labeling/packaging and reprocessing/investigating product nonconformance; and 15 percent goes to quality audit, traceability, handling, distribution, statistical, and other requirements.

Dated: June 28, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13152 Filed 7–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0357]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 7, 2007 (72 FR 10222), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0354. The approval expires on June 30, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: June 28, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13153 Filed 7–6–07; 8:45 am]

BILLING CODE 4160–01–S