reuse or remanufacture devices are now considered manufacturers under new FDA guidance. It is estimated that out of the 6,000 hospitals in the United States, one-third of them (or 2,000 hospitals) will reuse or remanufacture single use medical devices. Thus, the number of manufacturers will increase from 5,463 to 7,463 making the total number of firms subject to CGMP's 9,229.

• Potentially affected establishments: Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to quality policy (§ 820.20(a)), document control (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to part 820 Subpart C—Design Controls. The type of firm subject to each requirement was identified by ERG.

FDA estimated the burden hours (and costs) for the previous CGMP regulation in 1992. That estimate was submitted to OMB on May 4, 1992, under OMB Paperwork Reduction Act submission No. 0910–0073. It was approved by OMB on July 16, 1992, and it expired on June 30, 1995. The methodology used is different than that used by ERG in estimating incremental tasks when the new CGMP/QS became a final rule. Nevertheless, the agency believes its 1992 estimate adequately represents labor hours (and costs) needed to comply with previous CGMP requirements carried over into the new CGMP/QS regulation. The 1992 estimate used 9,289 respondents (rather than 9,229 respondents), which compensates for differences in methodology.

FDA estimates that some 650 ''new'' establishments (marketing devices for the first time) will expend some 114,882 ''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: 40 percent—to requirements dealing with manufacturing specifications, process controls and the DHR; 20 percent—to requirements dealing with components and acceptance activities; 25 percent—to requirements dealing with equipment, records (the DMR and QSR), complaint investigations, labeling/packaging and reprocessing/investigating product nonconformance; and 15 percent—to quality audit, traceability, handling, distribution, statistical, and other requirements.

Dated: February 22, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–4850 Filed 2–27–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0069]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information From U.S. Processors That Export to the European Community

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 the maintenance of lists of U.S. processors that export certain animal-derived foods (i.e., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to the European Community (EC), temporary exemptions from certain food labeling requirements for the purpose of conducting authorized food labeling experiments, petitions for health claims, and petitions for nutrient content claims.

DATES: Submit written or electronic comments on the collection of information by April 30, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. 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.

Request for Information From U.S. Processors That Export to the European Community (OMB Control Number 0910–0320)—Extension

EC is a group of 15 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intra-EC trade has been extended to trade with non-EC countries, including the United States. For certain food products, including those listed below in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

With the assistance of trade associations and State authorities, FDA requests information from processors

that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the list are subject to detention and possible refusal at the port. FDA requests the following information from each processor:

1. Business name and address;
2. Name and telephone number of person designated as business contact;
3. Lists of products presently being shipped to EC and those intended to be shipped in the next 6 months;
4. Name and address of manufacturing plants for each product;
5. Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier, such as plant number, and last date of inspection; and
6. Assurance that the firm or individual representing the firm and submitting a certificate for signature to FDA is aware of and knows that they are subject to the provisions of section 1001 of Title 18, United States Code. This law provides that it is a criminal offense to knowingly and willfully make a false statement or alter or counterfeit documents in a matter within the jurisdiction of a U.S. agency.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Products	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Shell eggs	10	1	10	0.25	2.5
Dairy	100	1	100	0.25	25
Game meat and meat products	10	1	10	0.25	2.5
Animal casings	15	1	15	0.25	3.75
Gelatin	6	1	6	0.25	1.5
Total					35.25

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

The estimated number of respondents is based on the volume of exports and responses received to date. The estimated number of yearly responses has decreased from the estimate in FDA's previous notice seeking comment for this collection of information (63 FR 29738, June 1, 1998) because the actual number of responses has been decreasing. Companies do not need to reapply unless they have a compliance problem. An estimate for processors that export gelatin also has been added because these processors are now being included in the listing process.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN (THIRD PARTY DISCLOSURE)[1]

Respondents	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Trade association	15	1	15	8	120
State	50	1	50	8	400
Total					520

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

The burden estimated for the trade associations assumes the trade associations will disseminate FDA's information request through mass mailings to their membership or publish it in their trade magazine or newsletter. The burden estimated for State authorities assumes dissemination of information to the processors or dissemination of information about processors to FDA.

Dated: February 22, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–4851 Filed 2–27–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1440]

Agency Information Collection Activities; Announcement of OMB Approval; User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''User Fee Cover Sheet'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 5, 2000 (65 FR 75942), 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 0910–0297. The approval expires on February 29, 2004.