

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN
[Registered licensed mixer-feeders] ¹

21 CFR section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.42(b)(5) through (b)(8)	100	260	26,000	.15	3,900
225.58(c) and (d)	100	36	3,600	.5	1,800
225.80(b)(2)	100	48	4,800	.12	576
225.102(b)(1)	100	260	26,000	.4	10,400
Total					16,676

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

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN
[Nonregistered unlicensed commercial feed mills] ¹

21 CFR section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.142	8,000	4	32,000	1	32,000
225.158	8,000	1	8,000	4	32,000
225.180	8,000	96	768,000	.12	92,160
225.202	8,000	260	2,080,000	.65	1,352,000
Total					1,508,160

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN
[Nonregistered unlicensed mixer-feeders] ¹

21 CFR section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
225.142	45,000	4	180,000	1	180,000
225.158	45,000	1	45,000	4	180,000
225.180	45,000	32	1,440,000	.12	172,800
225.202	45,000	260	11,700,000	.33	3,861,000
Total					4,393,800

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

The estimate of the times required for record preparation and maintenance is based on Agency communications with industry. Other information needed to finally calculate the total burden hours (*i.e.*, number of recordkeepers, number of medicated feeds being manufactured, etc.) is derived from Agency records and experience.

Dated: February 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0536]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Pharmacogenomic Data Submissions; Extension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 9, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0557. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, Elizabeth.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Pharmacogenomic Data Submissions—(OMB Control Number 0910–0557)—Extension

The guidance provides recommendations to sponsors submitting or holding investigational new drug applications (INDs), new drug applications (NDAs), or biologics license applications (BLAs) on what pharmacogenomic data should be submitted to the Agency during the drug development process. Sponsors holding and applicants submitting INDs, NDAs, or BLAs are subject to FDA requirements for submitting to the Agency data relevant to drug safety and efficacy (21 CFR 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12).

The guidance interprets FDA regulations for IND, NDA, or BLA submissions, clarifying when the regulations require pharmacogenomics data to be submitted and when the

submission of such data is voluntary. The pharmacogenomic data submissions described in the guidance that are required to be submitted to an IND, NDA, BLA, or annual report are covered by the information collection requirements under parts 312, 314, and 601 (21 CFR parts 312, 314, and 601) and are approved by OMB under control numbers 0910–0014 (part 312—INDs); 0910–0001 (part 314—NDAs and annual reports); and 0910–0338 (part 601—BLAs).

The guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decisionmaking, and other, less well-developed exploratory tests. The submission of exploratory pharmacogenomic data is not required under the regulations, although the Agency encourages the voluntary submission of such data.

The guidance describes the voluntary genomic data submission (VGDS) that can be used for such a voluntary submission. The guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated as a VGDS. The data submitted in a VGDS and the

level of detail should be sufficient for FDA to be able to interpret the information and independently analyze the data, verify results, and explore possible genotype-phenotype correlations across studies. FDA does not want the VGDS to be overly burdensome and time-consuming for the sponsor.

FDA has estimated the burden of preparing a voluntary submission described in the guidance that should be designated as a VGDS. Based on FDA’s experience with this guidance over the past few years, and on FDA’s familiarity with sponsors’ interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately seven sponsors will submit approximately one VGDS and that, on average, each VGDS will take approximately 50 hours to prepare and submit to FDA.

In the **Federal Register** of November 4, 2010 (75 FR 67983), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

	Number of Respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Voluntary Genomic Data Submissions	7	1	7	50	350

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

Dated: January 26, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
 [FR Doc. 2011–2637 Filed 2–4–11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0645]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use; 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: Contact Cooling System for Aesthetic Use.” This guidance document describes a means by which contact cooling systems for aesthetic use 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 contact cooling systems for aesthetic use into class II (special controls). The guidance document is immediately in effect as the special control for cooling system for aesthetic use, but it remains subject to comment in accordance with the Agency’s good guidance practices (GGPs).

DATES: Submit electronic or written comments on the guidance at any time. General comments on Agency guidance are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use” to the Division of Small Manufacturers,

International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Richard Felten, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1436, Silver Spring, MD 20993–0002, 301–796–6392.

SUPPLEMENTARY INFORMATION: