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]

BILLING CODE 4160–01–P

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:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying contact cooling systems for aesthetic use into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)). The guidance document will serve as the special control for contact cooling systems for aesthetic use device. Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C 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 FD&C Act, request that FDA classify the device under the criteria set forth in section 513(a)(1) of the FD&C 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 FD&C 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 the guidance as a final guidance document. Therefore, FDA is issuing the 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

The guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the Agency's current thinking on contact cooling systems for aesthetic use. 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

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. To receive a hard copy of "Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use," you may send a fax request to 301–847–8149. Please use the document number 1734 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The 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 812 have been approved under OMB control number 0910–0078; the collection of information 21 CFR 50.23 have been approved under OMB control number 0910–0586; the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; 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 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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: February 1, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–2553 Filed 2–4–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0066]

Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 8 and 9, 2011, from 8 a.m. to 6 p.m.

Addresses: FDA is opening a docket for public comment on this document. The docket will open for public comment on February 7, 2011, and will close on March 1, 2011. Interested persons are encouraged to use the docket to submit either electronic or written comments regarding this meeting. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6313, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory