

**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: 202-395-6974, or e-mailed to [baguilar@omb.eop.gov](mailto:baguilar@omb.eop.gov). All comments should be identified with the OMB control number 0910-0359. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**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.

**Reports of Corrections and Removals—21 CFR Part 806; (OMB Control Number 0910-0359)—Extension**

The collection of information required under the reports of corrections and removals, part 806 (21 CFR part 806), implements section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)), as amended by the Food and Drug Modernization Act of 1997 (FDAMA) (21 U.S.C. 301) (Public Law 105-115). Each device manufacturer or importer under § 806.10 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. Each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.20 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 devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals and to determine whether recall action is adequate.

In the **Federal Register** of December 11, 2007 (72 FR 70327), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

**TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>**

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	488	1	488	10	4,880
Total					4,880

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

**TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>**

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
806.20	132	1	132	10	1,320
Total					1,320

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

In preparing the previous clearances for approval of the information collection requirements under §§ 806.10 and 806.20, FDA reviewed the reports of corrections and removals submitted for the previous 3 years under part 7 (21 CFR part 7), the agency's recall provisions. FDA has determined that estimates of the reporting burden in § 806.10 should be revised to reflect a 1.2 percent increase for reports and records submitted under part 7 due to a decrease in class I and class II recall actions. FDA also estimates the reporting burden in § 806.20 should be revised to reflect a reduction of 8 percent for reports and records submitted under part 7 due to a decrease in class III recall actions. The time needed to collect information has not been changed.

Dated: April 4, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2008-N-0202] (formerly Docket No. 2008N-0009)**

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Customer/Partner Service Surveys**

**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 May 12, 2008.

**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: 202-395-6974, or e-mailed to [baguilar@omb.eop.gov](mailto:baguilar@omb.eop.gov). All comments should be identified with the OMB control number 0910-0360. Also include the FDA docket number found

in brackets in the heading of this document.

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

**Customer/Partner Service Surveys—(OMB Control Number 0910-0360)—Extension**

Under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research and public information programs about regulated products and responsibilities of the agency. Executive

Order 12862, entitled “Setting Customer Service Standard,” directs Federal agencies that “provide significant services directly to the public” to “survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.” FDA is seeking OMB clearance to conduct a series of surveys to implement Executive Order 12862. Participation in the surveys is voluntary. This request covers customer/partner service surveys of regulated entities, such as food processors; cosmetic drug, biologic and medical device manufacturers; consumers; and health professionals. The request also covers “partner” (State and local governments) customer service surveys.

FDA will use the information from these surveys to identify strengths and weaknesses in service to customers/

partners and to make improvements. The surveys will measure timeliness, appropriateness and accuracy of information, courtesy, and problem resolution in the context of individual programs.

FDA estimates conducting 15 customer/partner service surveys per year, each requiring an average of 18 minutes for review and completion. We estimate respondents to these surveys to be between 50 and 6,000 customers. Some of these surveys will be repeats of earlier surveys for purposes of monitoring customer/partner service and developing long-term data.

In the **Federal Register** of January 24, 2008 (73 FR 4234), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Type of Survey	No. of Respondents	Annual Frequency per Response	Hours per Response	Total Hours
Mail, telephone, fax, web-based	15,000	1	.30	4,500

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

Dated: April 4, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-7640 Filed 4-9-08; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-D-0205] (formerly Docket No. 2004D-0465)

**Guidance for Food and Drug Administration Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs),” dated April 2008.

The guidance document provides to sponsors recommendations on the CMC information to include in an original IND for human gene therapy. In addition, the guidance provides instructions to FDA reviewers about the information to record and assess as part of the IND review. The guidance document announced in this notice finalizes the draft guidance of the same title dated November 2004.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit

electronic comments to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Tami Belouin, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a document entitled “Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs),” dated April 2008. The guidance document provides to sponsors of a human gene therapy IND recommendations on the CMC information to include in an original IND. In addition, the guidance provides instructions to FDA reviewers about the information to record and assess as part of the IND review. This guidance will help sponsors and FDA reviewers to assess, given the phase of the investigation, whether sufficient information is provided to assure the proper identification, quality, purity, and potency of the investigational product.

In the **Federal Register** of November 9, 2004 (69 FR 64958), FDA announced