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[1]

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

[1] 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]

BILLING CODE 4160–01–S

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

the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and FDA considered those comments when finalizing the guidance. In addition, we revised the guidance to clarify its applicability for sponsors. The guidance announced in this notice finalizes the draft guidance dated November 2004.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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 statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 211.100, 211.160, and 211.165(e) have been approved under OMB Control No. 0910–0139; 21 CFR 312.23(a) and (b), 312.32(c), and Form FDA 1571 have been approved under OMB Control No. 0910–0014; and 21 CFR part 1271 has been approved under OMB Control No. 0910–0559.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: April 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–7585 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–0206] (formerly Docket No. 2003D–0349)

Guidance for Food and Drug Administration Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control Information for Human Somatic Cell 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 Somatic Cell 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 somatic cell therapy. In addition, the guidance provides instructions to FDA reviewers about information to record and assess as part of the IND review. The guidance announced in this notice finalizes the draft guidance entitled ''Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Control Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications'' dated August 2003.

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 Somatic Cell Therapy Investigational New Drug Applications (INDs),'' dated April 2008. The guidance document provides to sponsors of a human somatic cell therapy IND recommendations on the CMC information to include in an original IND. In addition, the guidance provides instructions to FDA reviewers about 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 August 18, 2003 (68 FR 49488), FDA announced the availability of the draft guidance entitled ''Draft Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Control Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications'' dated August 2003. FDA received several comments on the draft guidance and FDA considered those comments when finalizing the guidance. In addition, we revised the guidance to clarify its applicability for sponsors. The guidance announced in this notice finalizes the draft guidance dated August 2003.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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