regulation or an effective notification. The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made, (2) detailed information on the conditions of use of the substance, (3) a clear statement of the basis for the request for exemption from regulation as a food additive, (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance, (5) results of a literature search for toxicological data on the substance and its impurities, and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.39	15	1	15	48	720

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

In compiling these estimates, FDA consulted its records of the number of regulation exemption requests received in the past 3 years. The annual hours per response reporting estimate is based on information received from representatives of the food packaging and processing industries and agency records.

FDA estimates that approximately 15 requests per year will be submitted under the threshold of regulation exemption process of § 170.39. The threshold of regulation process offers one advantage over the premarket notification process for food-contact substances established by section 409(h) of the act (OMB control number 0910–0495) in that the use of a substance exempted by the agency is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both the agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and FDA would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Division of Dockets Management and on the Internet at *http://www.cfsan.fda.gov*. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the agency has previously granted an exemption from the food additive listing regulation requirement.

Dated: December 29, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6 Filed 1–5–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0526]

International Conference on Harmonisation; Draft Guidance on E15 Terminology in Pharmacogenomics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''E15 Terminology in Pharmacogenomics.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance contains definitions of key terms in the discipline of pharmacogenomics and pharmacogenetics, namely genomic biomarkers, pharmacogenomics, pharmacogenetics, and genomic data and sample coding categories. In the effort to develop harmonized approaches to drug regulation, it is important to ensure that consistent definitions of terminology are being applied across all constituents of the ICH. The draft guidance is intended facilitate the integration of the discipline of pharmacogenomics and pharmacogenetics into global drug development and approval processes.

DATES: Submit written or electronic comments on the draft guidance by April 9, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed labels to assist the office in processing your requests. Submit written comments on the draft 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section

for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Felix Frueh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4512, Silver Spring, MD 20993–0002, 301–796–1530; or

Raj K. Puri, Center for Biologics Evaluation and Research (HFM–735), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0471.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labour, and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In October 2006, the ICH Steering Committee agreed that a draft guidance entitled ''E15 Terminology in Pharmacogenomics'' should be made available for public comment. The draft guidance is the product of the E15 Pharmacogenomics Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the E15 Pharmacogenomics Expert Working Group.

The draft guidance represents an international effort to harmonize pharmacogenomics definitions and sample coding. Inconsistent definitions make it difficult to achieve agreement on parameters for implementation of pharmacogenomics in global pharmaceutical development, and might lead to inconsistent assessments by regulators. The draft guidance contains definitions of key terms in the discipline of pharmacogenomics and pharmacogenetics, namely genomic biomarkers, pharmacogenomics, pharmacogenetics, and genomic data and sample coding categories. Timely harmonisation of terminology and definitions will create a common foundation for future guidance on pharmacogenomics.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency'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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: December 29, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Proposed Project: GPRA Client Outcomes for the Substance Abuse and Mental Health Services Administration (SAMHSA)—(OMB No. 0930–0208)—Revision.

The mission of the Substance Abuse and Mental Health Services Administration (SAMHSA) is to improve the effectiveness and efficiency of substance abuse and mental health treatment and prevention services across the United States. All of SAMHSA's activities are designed to ultimately reduce the gap in the availability of substance abuse and mental health services and to improve their effectiveness and efficiency.

Data are collected from all SAMHSA discretionary services grants and contracts where client/participant outcomes are to be assessed at three points (for the Center for Substance Abuse Treatment (CSAT): Intake, discharge, and post-intake and for the Center for Substance Abuse Prevention (CSAP): pre-intervention, post-intervention, and follow-up). SAMHSA-funded projects are required to submit these data as a contingency of their award. The analysis of the data also will help determine whether the goal of reducing health and social costs of drug use to the public is being achieved.

The primary purpose of this data collection activity is to meet the reporting requirements of the Government Performance and Results Act (GPRA) by allowing SAMHSA to quantify the effects and