TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

CFR Section	FDA Form No.	Number of respondents	Annual frequency of response	Total annual responses	Hours per response	Total hours
Exemptions—803.19		57	4	228	3	684
User Facility Reporting—803.30 and 803.32		544	9	4,896	1	4,896
User Facility Annual Reporting—803.33	FDA Form 3419	195	1	195	1	195
Importer Reporting, Death and Serious Injury—803.40 and 803.42		1	1	1	1	1
Manufacturer Reporting—803.50, through 803.53		1,239	243	301,077	1	301,077
Supplemental Reports—803.56		124	302	37,448	1	37,448
Total						344,301

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours
MDR Procedures—803.17	220	1	220	10	2,200
MDR Files—803.18	30,000	1	30,000	1.5	45,000
Total					47,200

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Importer Reporting, Malfunctions—803.40 and 803.42	1	25	25	1	25

Dated: June 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–13832 Filed 6–6–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0178]

International Conference on Harmonisation; Guidance on S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use'' (ICH S2(R1)). This guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The ICH S2(R1) combines and replaces two ICH guidances, ''S2A Specific Aspects for Regulatory Genotoxicity Tests for Pharmaceuticals'' and ''S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals.'' ICH S2(R1) provides guidance to drug sponsors on which tests should be performed to assess potential genotoxicity of pharmaceuticals. It also provides guidance on testing conditions, data interpretation, and followup strategies if a positive response is seen in in vitro assays. This guidance is intended to provide drug sponsors with recommendations to ensure that drugs are appropriately tested for potential to cause genetic damage and to ensure efficient development of new drugs.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (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 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.

FOR FURTHER INFORMATION CONTACT:

Regarding the Guidance

David Jacobson-Kram, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6488,

Silver Spring, MD 20993–0002, 301–796–0175.

Regarding the ICH

Michelle Limoli, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 3506, Silver Spring, MD 20993–0002, 301–796–4600.

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 the **Federal Register** of March 26, 2008 (73 FR 16024), FDA published a notice announcing the availability of a draft guidance entitled ''S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use.'' The notice gave interested persons an opportunity to submit comments by May 12, 2008.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory Agencies in November 2011.

The purpose of the ICH S2(R1) revision is to provide guidance on optimizing the standard genetic toxicology battery for prediction of potential human risks, and on interpreting results, with the goal of improving risk characterization for carcinogenic effects that have their basis in changes in the genetic material. The revised guidance describes internationally agreed-upon standards for followup testing and interpretation of positive results in vitro and in vivo in the standard genetic toxicology battery, including assessment of nonrelevant findings.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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**) either electronic or written comments regarding this document. It is only necessary to send one set 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: June 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–13774 Filed 6–6–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of a Noncompetitive Supplement and a 7-Month Extension of the Period of Support for the Frontier Extended Stay Clinic (FESC) Cooperative Agreement Recipient—SouthEast Alaska Regional Health Consortium

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of a Noncompetitive Supplement and a 7-Month Extension of the Period of Support for the Frontier Extended Stay Clinic (FESC) Cooperative Agreement Recipient—SouthEast Alaska Regional Health Consortium.

SUMMARY: The Health Resources and Services Administration (HRSA) will be issuing a non-competitive supplement and a 7-month extension of the period of support to the Frontier Extended Stay Clinic (FESC) Cooperative Agreement recipient of record, SouthEast Alaska Regional Health Consortium (Grant Number U17RH23237). The FESC Cooperative Agreement helps to examine the effectiveness and appropriateness of a new type of provider, FESC, in providing health care services in remote areas. The 7-month extension with funds will align with the related three-year Centers for Medicare and Medicaid Services (CMS) demonstration, which will run until March 2013.

SUPPLEMENTARY INFORMATION: The recipient of record and intended award amount is: