U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of ''CDC Grants for Public Health Research Dissertation (Panel A–3), PAR07–231.''

Contact Person for More Information: Sheree Marshall Williams, Ph.D., M.Sc., Scientific Review Administrator, CDC, 1600 Clifton Road, NE., Mailstop D72, Atlanta, GA 30333, Telephone (404) 639–4896.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 6, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–13185 Filed 6–11–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Plan for Foster Care, Independent Living Services and Adoption Assistance under Title IV–E of the Social Security Act.

OMB No.: 0980–0141.

Description: A State plan is required by sections 471 and 477(b)(2), part IV–E of the Social Security Act (the Act) for each public child welfare agency requesting Federal funding for foster care, independent living services and adoption assistance under the Act. The State plan is a comprehensive narrative description of the nature and scope of a State's programs and provides assurances the programs will be administered in conformity with the specific requirements stipulated in title IV–E. The plan must include all applicable State statutory, regulatory, or policy references and citation for each requirement as well as supporting documentation. A State may use the pre-print format prepared by the Children's Bureau of the Administration for Children and Families or a different format on the condition that the format used includes all of the title IV–E State plan requirements of the Act.

Respondents: State and Territorial Agencies (State Agencies) administering or supervising the administration of the title IV–E program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV–E State Plan	13	1	15	195

Estimated Total Annual Burden Hours: 195.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project.

Fax: 202–395–6974,

Attn: Desk Officer for the Administration for Children and Families.

Dated: June 5, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–13089 Filed 6–11–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2001–D–0067] (formerly Docket No. 2001D–0185)

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Postmarketing Individual Case Safety Reports; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Individual Case Safety Reports.'' This draft guidance consolidates and revises information in two existing draft guidances pertaining to electronic submission of postmarketing individual case safety reports (ICSRs) and attachments to ICSRs (ICSR attachments). The submission of ICSRs and ICSR attachments in an electronic format significantly improves the agency's efficiency in processing, archiving, and reviewing the reports.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance, including comments regarding proposed collection of information, by August 11, 2008.

ADDRESSES: Submit written requests for single copies of the draft 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 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 that office in processing your

requests. The guidance may also be obtained by calling CBER at 1–800–835–4709 or 301–827–1800. 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Roger Goetsch, Center for Drug Evaluation and Research (HFD–410), Food and Drug Administration, 12300 Twinbrook Pkwy., suite 240, Rockville, MD 20851, 301–770–9299; or

Steven Ripley, Center for Biologics Evaluation and Research (HFM–17),Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852,301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Individual Case Safety Reports'' (the electronic ICSR draft guidance). The electronic ICSR draft guidance will apply to drug products marketed for human use with approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs); prescription drug products marketed for human use without an approved NDA or ANDA; nonprescription drug products marketed without an approved application; biological products, including therapeutic vaccines, marketed for human use with approved biologic license applications (BLAs) and submission tracking numbers (STNs); and human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264). The electronic ICSR draft guidance will not apply to prophylactic vaccines, whole blood, or components of whole blood.

A. Consolidation of Earlier Guidance

This electronic ICSR draft guidance consolidates and revises information pertaining to electronic submission of postmarketing ICSRs and ICSR attachments in the following guidances:

- Draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports'' issued in May 2001 (Expedited Reports draft guidance) (66 FR 22585, May 4, 2001), and
- Draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports'' issued in June 2003 (Periodic Reports draft guidance) (68 FR 37504, June 24, 2003).

The electronic ICSR draft guidance replaces the Expedited Reports draft guidance in its entirety, and we have removed the Expedited Reports draft guidance from the Center for Drug Evaluation and Research (CDER) and CBER's guidance pages. The electronic ICSR draft guidance also replaces the ICSR and ICSR attachment portion of the Periodic Reports draft guidance, but does not address the descriptive information portion. We have removed the Periodic Reports draft guidance from CDER and CBER's guidance pages. For information on electronic submission of the descriptive information portion of periodic adverse drug experience reports, see the section on periodic safety update reports in the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (see Revision 2, June 2008).

B. International Standards for Electronic Transmission

FDA has cooperated with industry associations, standards development organizations, and the regulatory authorities of certain other nations to promote international harmonization of regulatory requirements. Much of this effort has been coordinated through the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Under the auspices of the ICH, standards for electronic submission of safety information for human drug and biological products have been developed. This draft guidance is intended to provide guidance to industry regarding submission of postmarketing ICSRs and ICSR attachments to FDA in electronic form using the standards established by the ICH.

C. Updated Recommendations

As a result of comments received on the Expedited Reports and Periodic Reports draft guidances, as well as evolving technology, a number of substantive changes have been made to the agency's recommendations for the electronic transmission of ICSRs and ICSR attachments. In addition to consolidating all the information pertaining to electronic submission of ICSRs and ICSR attachments into a single guidance, the electronic ICSR draft guidance also provides references to technical specifications for these submissions.

Since the Expedited Reports and Periodic Reports draft guidances were issued, the agency has received ICSRs for HCT/Ps regulated under section 361 of the PHS Act. On December 22, 2006, the President signed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462), which amended the Federal Food, Drug, and Cosmetic Act to add safety reporting requirements for nonprescription drug products marketed without an approved application (21 U.S.C. 379aa). The recommendations in this electronic ICSR draft guidance will apply to these products as well as to products with approved NDAs, ANDAs, BLAs and STNs, and prescription drug products marketed without an approved NDA or ANDA.

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 providing postmarketing ICSRs and ICSR attachments in electronic format. 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 regarding this document. 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.

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 only through FDMS at *http://www.regulations/gov*.

III. Paperwork Reduction Act of 1995

This electronic ICSR draft guidance refers to proposed collections of information required by Public Law 109–462 and 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). As required by the PRA, FDA is now requesting public comment (see **DATES**) on these proposed collections of information. The agency's analysis and estimates of the proposed collections of information in the electronic ICSR draft guidance that are required by Public Law 109–462 have been described previously in FDA's notice of availability for a draft guidance entitled ''Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application'' (72 FR 58316, October 15, 2007) (the October 2007 PRA analysis). For burden estimates for the proposed collections of information in the electronic ICSR draft guidance, see the October 2007 PRA analysis.

This electronic ICSR draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 310.305, 314.80, 600.80, and 1271.350 have been approved under OMB control numbers 0910–0291, 0910–0230, 0910–0308, and 0910–0543 respectively.

IV. Electronic Access

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

Dated: June 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–13269 Filed 6–11–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0339]

Draft Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices.'' The Food and Drug Administration Amendments Act of 2007 (FDAAA) includes a requirement that FDA identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and make those findings publicly available. This draft guidance informs industry of how FDA intends to comply with the FDAAA requirement. Specifically, the draft guidance describes procedures and responsibilities for updating information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use. This draft guidance also describes procedures for making corresponding changes to susceptibility test interpretive criteria for antimicrobial susceptibility testing (AST) devices.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by August 11, 2008. Submit written comments on the proposed collection of information by August 11, 2008.

ADDRESSES: Submit written requests for single copies of the draft 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 Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850–4307. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance, including comments regarding proposed collection of information, 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding antibacterial drug products: Edward Cox, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6414, Silver Spring, MD 20993–0002, 301–796–1300, or

Regarding AST devices: Freddie Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0712.

SUPPLEMENTARY INFORMATION:

I. Background

Antibacterial susceptibility testing is used to determine if bacteria that are isolated from a patient with an infection are likely to be killed or inhibited by a particular antibacterial drug product at the concentrations of the drug that are attainable at the site of infection using the dosing regimen(s) indicated in the drug product's labeling. The results from antibacterial susceptibility testing generally categorize bacteria as ''susceptible,'' ''intermediate,'' or ''resistant'' to each of the antibacterial drugs that are tested. When available, culture and susceptibility testing results are one of the factors that physicians consider when selecting an antimicrobial drug product for treating a patient.

The numerical values generated by susceptibility testing to determine whether a particular microorganism is susceptible to a particular antimicrobial drug—the antimicrobial susceptibility test interpretive criteria—are commonly referred to as breakpoints. These breakpoints are specified in the antimicrobial drug product's label. The antimicrobial susceptibility test interpretive criteria can be used to interpret results from either manual or automated AST devices.

On September 27, 2007, the President signed FDAAA (Public Law 110–85) into law. Section 1111 of FDAAA requires FDA to identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and to make those findings publicly available. By enacting section 1111 of FDAAA, Congress recognized the importance of maintaining updated susceptibility test interpretive criteria.

FDA is announcing the availability of a draft guidance for industry entitled ''Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices'' to inform industry of how FDA intends to comply with section 1111 of FDAAA. The draft guidance explains