Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6144, Silver Spring, MD 20993–0002, 301–796–5400; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Postmarketing Studies and Clinical Trials—Implementation of Section 505(o) of the Federal Food, Drug, and Cosmetic Act.'' In the past, FDA has used the term ''PMC'' to refer to studies (including clinical trials), conducted by an applicant after FDA has approved a drug for marketing or licensing, that were intended to further refine the safety, efficacy, or optimal use of a product, or to ensure consistency, and reliability of product quality. These commitments were either agreed upon by FDA and the applicant or, in certain circumstances, required by FDA. Prior to the passage of FDAAA, FDA required PMCs in the following situations:

- Subpart H and subpart E accelerated approvals, which require postmarketing studies to demonstrate clinical benefit (21 CFR 314.510 and 601.41);
- Deferred pediatric studies, where studies are required under the Pediatric Research Equity Act (PREA) (21 CFR 314.55(b) and 601.27(b)); and
- Animal Efficacy Rule approvals, where studies to demonstrate safety and efficacy in humans are required at the time of use (21 CFR 314.610(b)(1) and 601.91(b)(1)).

Title IX, section 901 of FDAAA (Public Law 110–85) amended the act by adding new section 505(o) (21 U.S.C. 355(o)). Section 505(o) of the act authorizes FDA to require certain postmarketing studies or clinical trials for prescription drug and biological products approved under section 505 of the act or section 351 of the PHS Act (42 U.S.C. 262). Section 505(o)(3)(B) of the act states that postmarketing studies and clinical trials may be required for one of three purposes:

- To assess a known serious risk related to the use of the drug;
- To assess signals of serious risk related to the use of the drug; or
- To identify an unexpected serious risk when available data indicates the potential for a serious risk.

This draft guidance provides information on the implementation of new section 505(o) of the act. The draft guidance also describes which types of postmarketing studies and clinical trials will be required (PMRs) under section 505(o) of the act and which types will be agreed-upon commitments because they do not meet the statutory criteria for required studies and trials (PMCs).

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 the implementation of section 901 of FDAAA on postmarketing studies and clinical trials. 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.

III. Paperwork Reduction Act of 1995

This draft guidance provides information on the implementation of section 901 of FDAAA. The collections of information requested in the draft guidance would be submitted under 21 CFR 314.80, 314.81, and 601.70. 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) and are approved under OMB control numbers 0910–0230, 0910–0001, and 0910–0338. Section VI of the draft guidance refers to procedures in the guidance entitled ''Formal Dispute Resolution: Appeals Above the Division Level,'' which contains collections of information approved under OMB control number 0910–0430.

IV. Electronic Access

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

Dated: July 2, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16867 Filed 7–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–D–0021 (formerly Docket No. 1998D–0514)]

Guidance for Industry on Abbreviated New Drug Applications: Impurities in Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''ANDAs: Impurities in Drug Substances,'' which is a revision of a guidance for industry of the same name that published in November 1999. The guidance provides recommendations for applicants on what chemistry, manufacturing, and controls (CMC) information to include regarding the reporting, identification, and qualification of impurities in drug substances produced by chemical synthesis when submitting original abbreviated new drug applications (ANDAs); drug master files (DMFs), including type II DMFs; and ANDA supplements for changes in the synthesis or processing of a drug substance.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lawrence Yu, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9310.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised guidance for industry entitled ''ANDAs: Impurities in Drug Substances.'' The guidance provides revised recommendations on what CMC information to include regarding the reporting, identification, and qualification of impurities in drug substances produced by chemical synthesis when submitting: (1) Original ANDAs; (2) DMFs, including type II DMFs; and (3) ANDA supplements for changes in the synthesis or processing of a drug substance. The guidance also provides recommendations for establishing acceptance criteria for impurities in drug substances.

In November 1999, FDA published the first version of this guidance. In 2003, the International Conference on Harmonisation made changes to recommendations on impurities in drug substances for new drug applications in the guidance for industry entitled ''Q3A Impurities in New Drug Substances'' (Revision 1) (Q3A(R)). As a result of these changes, FDA began an effort to revise this guidance for ANDAs. FDA has revised the guidance to update information on listing impurities, setting acceptance criteria, and qualifying impurities (thresholds and procedures) in ANDAs to make it consistent with Q3A(R).

On January 31, 2005 (70 FR 4857), FDA announced the availability of the draft revision for public comment. The comment period closed on May 2, 2005. A number of comments were received, which the agency considered carefully as it began the process of finalizing the guidance.

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 impurities in drug substances for generic drugs. 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 an 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.

III. 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 part 314 have been approved under OMB Control No. 0910–0001.

IV. Electronic Access

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

Dated: July 7, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16868 Filed 7–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Board of Scientific Counselors, Coordinating Office for Terrorism Preparedness and Emergency Response (BSC, COTPER)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC announces the following meeting of the aforementioned committee:

Times and Dates: 12 p.m.–5:15 p.m., August 13, 2009; 9 a.m.–3:30 p.m., August 14, 2009.

Place: CDC, 1600 Clifton Road, NE., Global Communications Center, Building 19, Auditorium B3, Atlanta, Georgia 30333.

Status: Open to the public for observation and comment, limited only by the space available. The meeting room accommodates approximately 50 people. Visitors to the CDC campus must be processed in accordance with established Federal policies and procedures and should pre-register for the meeting as described in Additional Information for visitors. Public comment periods are planned for both meeting days.

Purpose: This Board is charged with advising the Secretary of HHS and Director of CDC concerning strategies and goals for the programs and research within COTPER, monitoring the strategic direction and focus of the Divisions, and conducting peer review of scientific programs. For additional information about the COTPER BSC, please visit: *http://emergency.cdc.gov/cotper/science/counselors.asp.*

Matters To Be Discussed: A program response to the Board's recommendations from the external peer review of the fiscal allocation process; a briefing on the findings of the external peer review of COTPER's Division of Select Agents and Toxins; status updates on other external peer reviews of COTPER programs; updates from COTPER activities and programs; and a discussion of external peer review topics for fiscal year 2010. Agenda items are subject to change as priorities dictate.

Additional Information For Visitors: All visitors are required to present a valid form of picture identification issued by a State, Federal or international government. To expedite the security clearance process for visitors to the CDC Roybal campus, all visitors must pre-register by submitting the following information by e-mail or phone (see Contact Person for More Information) no later than 12 noon (EDT) on Monday, July 27, 2009:

- Full Name,
- Organizational Affiliation,
- Complete Mailing Address,
- Citizenship, and
- Phone Number or E-mail Address.

For foreign nationals or non-U.S. citizens, pre-approval is required. Please contact the BSC Coordinator (see Contact Person for More Information) in advance of the posted pre-registration deadline for additional security requirements that must be met.

Contact Person for More Information: Matthew Jennings, BSC Coordinator, COTPER, CDC, 1600 Clifton Rd., NE., Mailstop D–44, Atlanta, GA 30333, *Telephone:* (404) 639–7357; *Facsimile:* (404) 639–7977; *E-mail: COTPER.BSC.Questions@cdc.gov.*

The Director, Management Analysis and Service 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 Agency for Toxic Substances and Disease Registry.

Dated: July 7, 2009.

Elaine L. Baker,

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

[FR Doc. E9–16771 Filed 7–14–09; 8:45 am]

BILLING CODE 4163–18–P