

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2013-N-0853]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practice; Quality System Regulation****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRASaff@fda.hhs.gov](mailto:PRASaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On December 19, 2013, the Agency submitted a proposed collection of information entitled "Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0073. The approval expires on February 28, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 14, 2014.

**Leslie Kux,***Assistant Commissioner for Policy.*

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[Docket No. FDA-2011-D-0720]

**International Conference on Harmonisation; E2B(R3) Electronic Transmission of Individual Case Safety Reports; Data Elements and Message Specification; Appendix on Backwards and Forwards Compatibility; 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 "E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs): Implementation Guide—Data Elements and Message Specification" (the E2B(R3) implementation guidance) and an appendix to the guidance entitled "ICSRs: Appendix to the Implementation Guide—Backwards and Forwards Compatibility" (the BFC appendix). The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The E2B(R3) implementation guidance is intended to revise the standards for submission of ICSR reports and improve the inherent quality of the data, enabling improved handling and analysis of ICSR reports. The BFC appendix describes the relationship between data elements from the 2001 ICH E2B guidance and the E2B(R3) implementation guidance.

**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 (HFD-240), Center for Drug Evaluation and Research (CDER), 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:* Roger Goetsch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 22, Rm. 4491, Silver Spring, MD 20993-0002, 240-402-3730; or Lise Stevens, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-2743, *Regarding the ICH:* Michelle Limoli, Center for Drug Evaluation and Research, International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3342, Rockville, MD 20993-0002, 301-796-8377.

**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; CDER and CBER, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the