



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 314, 329, and 600

[Docket No. FDA-2008-N-0334]

RIN 0910-AF96

Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; Delay of Compliance Date; Safety Reporting Portal of Electronic Submission of Postmarketing Safety Reports for Human Drugs and Nonvaccine Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of compliance date.

SUMMARY: The Food and Drug Administration (FDA or Agency) is delaying the compliance date for the final rule for the electronic submission of postmarketing safety reports for human drugs and biological products that published in the Federal Register of June 10, 2014. The rule amended FDA's postmarketing safety reporting regulations for human drugs and biological products to require that persons subject to mandatory reporting requirements submit safety reports in an electronic format that FDA can process, review, and archive. FDA is also announcing the availability of the Safety Reporting Portal (SRP), a Web-based electronic submission system, for the electronic submission of postmarketing individual case safety reports (ICSRs) of adverse events for human drug and nonvaccine biological products. The SRP is intended to facilitate the secure electronic submission of postmarketing

ICSRs and ICSR attachments to the FDA Adverse Event Reporting System (FAERS) database. The SRP creates a simple and efficient mechanism for electronic reporting of ICSRs that does not require an internal database that is compatible with the International Conference on Harmonisation-based direct submission system. FDA is delaying the compliance date for the final rule because FDA understands that not all persons subject to mandatory postmarketing reporting requirements who wish to use the newly available Safety Reporting Portal (SRP) will have the opportunity to register for an account and test the submission process prior to June 10, 2015, the effective date of the final rule.

DATES: Effective Date: This final rule is effective June 10, 2015. Compliance Date: The compliance date for the final rule published at 79 FR 33072 on June 10, 2014, is delayed until September 8, 2015.

FOR FURTHER INFORMATION CONTACT: Suranjan De, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4307, Silver Spring, MD 20993-0002, 240-402-0498, email: FAERSEUBS@fda.hhs.gov, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA published in the Federal Register of June 10, 2014 (79 FR 33072), a final rule requiring electronic submission of certain postmarketing submissions (the final rule) and also published an accompanying revised draft guidance for industry “Providing Submissions in Electronic Format--

Postmarketing Safety Reports” (79 FR 33200) (June 2014 revised draft guidance).¹ The final rule becomes effective June 10, 2015. Under the final rule, persons subject to mandatory postmarketing reporting requirements are required to submit postmarketing ICSRs to FDA in an electronic format that the Agency can process, review, and archive. Postmarketing ICSRs and ICSR attachments sent to FDA for human drug and nonvaccine biological products are processed into the FAERS database. As discussed in the preamble to the final rule, FDA provides two options for electronic submission of ICSRs to FAERS to satisfy the requirement in the final rule that persons subject to mandatory postmarketing reporting requirements submit postmarketing ICSRs to FDA in an electronic format that the Agency can process, review, and archive: (1) Direct submission through the Electronic Submissions Gateway, and (2) submission through the SRP. Persons subject to mandatory postmarketing reporting requirements can choose to use these options to meet the requirements of the final rule to electronically submit postmarketing ICSRs to FAERS.

At this time, FDA is announcing the availability of the SRP, a Web-based electronic submission system, for the electronic submission of postmarketing ICSRs of adverse events for human drug and nonvaccine biological products.

To use the SRP, the ICSR information is entered manually into a Web-based form and then submitted to FDA to be uploaded into the FAERS database. The SRP may be used by any persons subject to mandatory postmarketing safety reporting requirements, including manufacturers, packers, and distributors, and applicants with approved new drug applications (NDAs), abbreviated new drug

¹ The June 2014 revised draft guidance is available on the Drugs guidance Web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> and on the FAERS Electronic Submissions Web page at <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ucm115894.htm>.

applications (ANDAs), and biologics license applications (BLAs), those that market prescription drugs for human use without an approved application including entities that are registered with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353b), and those subject to the reporting requirements in section 760 of the FD&C Act (21 U.S.C. 379aa).

II. Discussion of Rationale for Delay

The Agency believes that the SRP may be particularly useful for those entities that submit a small volume of ICSRs because the SRP does not require an internal database that is compatible with the ICH-based direct transmission system. FDA understands that not all persons subject to mandatory postmarketing reporting requirements who wish to use the SRP will have the opportunity to register for an account and test the submission process prior to June 10, 2015, the effective date of the final rule. Therefore, while persons subject to mandatory postmarketing reporting requirements are going through the registration process, FDA is delaying the compliance date of the final rule until September 8, 2015. FDA will continue to accept postmarketing ICSRs submitted on paper Forms FDA 3500A for 90 calendar days from the June 10, 2015, effective date of the final rule. FDA expects full compliance with the final rule by Tuesday, September 8, 2015. FDA is delaying the compliance date for this rule directly, without issuing notice of proposed rulemaking or taking comments on this action, for good cause. Because not all persons who want to use the SRP will be able to do so prior to the June 10, 2015, effective date for this rule, and because this effective date is now imminent, we find that issuing notice and taking comments are impracticable, unnecessary, and contrary to the public interest with respect to this action.

III. Overview of the SRP

The SRP originated as a collaborative initiative developed by a multi-agency Federal Adverse Event Task Force, which included FDA as part of the Agency's MedWatch Plus strategic effort, starting in 2004. Submission of safety reports through the SRP is described on the FDA SRP Web Page (the SRP is available on the SRP Web page at <https://www.safetyreporting.hhs.gov/fpsr/WorkflowLoginIO.aspx?metinstance=0AA0751AD2587A59D28B14D5C764AC7CA68678FE>). The SRP is intended to create greater harmonization among Federal Agencies for adverse event and product problem reporting by streamlining and coordinating the currently diverse Federal requirements for the reporting and the review of adverse events.² Further information on submitting ICSRs through the SRP is included in FDA's June 2014 revised draft guidance.

² The origins and purpose of the SRP are discussed on the SRP Web page at <https://www.safetyreporting.hhs.gov/fpsr/About.aspx>.

Dated: May 20, 2015.

Leslie Kux,

Associate Commissioner for Policy,

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