14 CFR Part 414

Airspace, Aviation Safety, Space transportation and exploration.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter III of title 14, Code of Federal Regulations as follows:

PART 401—ORGANIZATION AND DEFINITIONS

■ 1. The authority citation for part 401 continues to read as follows:

Authority: 51 U.S.C. 50901–50923.

■ 2. In § 401.5, add a definition in alphabetical order for *physical electronic storage* to read as follows:

§ 401.5 Definitions.

* * * * *

Physical electronic storage means a physical device that can store electronic documents and files including but not limited to an optical disc, a memory card, a USB flash drive, or an external hard drive.

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PART 413—LICENSE APPLICATION PROCEDURES

■ 3. The authority citation for part 413 continues to read as follows:

Authority: 51 U.S.C. 50901–50923.

■ 4. In § 413.7, revise paragraph (a) to read as follows:

§ 413.7 Application.

(a) An applicant must make an application in writing and in English. The applicant must file the application with the Federal Aviation Administration either by paper, by use of physical electronic storage, or by email in the following manner:

(1) For applications submitted on paper, an applicant must send two copies of the application to the Federal Aviation Administration, Associate Administrator for Commercial Space Transportation, Room 331, 800 Independence Avenue SW., Washington, DC 20591. Attention: Application Review.

(2) For an application submitted by use of physical electronic storage, the applicant must either mail the application to the address specified in paragraph (a)(1) of this section or hand-deliver the application to an authorized FAA representative. The application and the physical electronic storage containing the application must also satisfy all of the following criteria:

(i) The application must include a cover letter that is printed on paper and signed by the person who signed the application or by an authorized representative of the applicant;

(ii) The cover letter must identify each document that is included on the physical electronic storage; and

(iii) The physical electronic storage must be in a format such that its contents cannot be altered.

(3) For an application submitted by email, an applicant must send the application as an email attachment to *ASTApplications@faa.gov.* The application and the email to which the application is attached must also satisfy the following criteria:

(i) The email to which the application is attached must be sent from an email address controlled by the person who signed the application or by an authorized representative of the applicant; and

(ii) The application must be in a format that cannot be altered.

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PART 414—SAFETY APPROVALS

■ 5. The authority citation for part 414 continues to read as follows:

Authority: 51 U.S.C. 50901–50923.

■ 6. In § 414.11, revise paragraph (a) to read as follows:

§ 414.11 Application.

(a) An applicant must make an application in writing and in English. The applicant must file the application with the Federal Aviation Administration either by paper, by use of physical electronic storage, or by email in the following manner:

(1) For an application submitted on paper, an applicant must send two copies of the application to the Federal Aviation Administration, Associate Administrator for Commercial Space Transportation, Room 331, 800 Independence Avenue SW., Washington, DC 20591. Attention: Application Review.

(2) For an application submitted by use of physical electronic storage, the applicant must either mail the application to the address specified in paragraph (a)(1) of this section or hand-deliver the application to an authorized FAA representative. The application and the physical electronic storage containing the application must also satisfy all of the following criteria:

(i) The application must include a cover letter that is printed on paper and signed by the person who signed the application or by an authorized representative of the applicant;

(ii) The cover letter must identify each document that is included on the physical electronic storage; and

(iii) The physical electronic storage must be in a format such that its contents cannot be altered.

(3) For an application submitted by email, an applicant must send the application as an email attachment to *ASTApplications@faa.gov.* The application and the email to which the application is attached must also satisfy the following criteria:

(i) The email to which the application is attached must be sent from an email address controlled by the person who signed the application or by an authorized representative of the applicant; and

(ii) The application must be in a format that cannot be altered.

* * * * *

Issued under authority provided by 49 U.S.C. 106(f), and 51 U.S.C. 50904–50905 in Washington, DC, on April 30, 2015.

Michael P. Huerta,

Administrator.

[FR Doc. 2015–12556 Filed 5–26–15; 8:45 am]

BILLING CODE 4910–13–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 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.

Dated: May 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12753 Filed 5–26–15; 8:45 am]

BILLING CODE 4164–01–P

[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.*

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