4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule entitled "Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements" that appeared in the Federal Register of June 10, 2014 (79 FR 33072). The document amended FDA's postmarketing safety reporting regulations for human drug 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. The document was published with incorrect information regarding the availability of the International Conference on Harmonization's (ICH) data elements for postmarketing safety reports. The document also published with an incorrect statement regarding the impact of the final rule on small entities. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4466, Silver Spring, MD 20993-0002, 301-796-1874; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7268, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

In the Federal Register of June 10, 2014, in FR Doc. 2014-13480, the following corrections are made:

1. On page 33074, in the first column, under "Introduction", footnote 6 is corrected to read: "ICH data elements for postmarketing safety reports are provided in the guidance for industry entitled 'E2B Electronic Transmission of Individual Case Safety Reports Implementation Guide--Data Elements and Message Specification,' available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm."

2. On page 33084, in the second column, under "Analysis of Impacts", the first full sentence is corrected to read: "Because the average small entity submits few safety reports and the Agency's Web-based system for submitting reports electronically will require little additional cost per report, the Agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities."

Dated: August 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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