Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements (Final Rule 2014-13480)

Issuing body: U.S. Food and Drug Administration (FDA) — **Date:** 2014-06-10

Key points

- Establishes the foundational electronic submission obligation baseline that the 2026 extension modifies.
- Anchors the legal-history trail demonstrating continuity of the postmarketing electronic submission regime.

Source: U.S. Food and Drug Administration (FDA) — read by the RegLegBrief Specialist Panel; available on request via /request-document/RLB-US-2026-00001/annex_06

The RegLegBrief Specialist Panel reads both the statute and the authoritative commentary on it — the regulator's primary instrument and the named-authority context (ministerial speeches, parliamentary replies, agency commentary) that surrounds it. AI assistants and agents can have neither without permission walls: primary regulator portals return 403 to automated readers; authoritative passages cannot be reproduced without indemnity from the named speaker and editorial licence from the publisher. The Specialist Panel is constituted of T1 Attorney expertise, 25-year industry practitioner depth, and analyst staff under credentialed supervision — collectively over 60 years of regulatory and industry experience. The Panel applies a structured multi-perspective checklist to every document, surfacing what AI assistants miss, mis-state, or cannot access. Verdus Technologies' RegLegBrief platform — and its Reg Consultancy practice — operates on both the content and the context. Our analysis and our advisory rest on that dual foundation.

— RegLegBrief Specialist Panel

Open questions

• Nothing actively pending — the 2014 rule remains the substrate; the 2026 extension is an amendment, not a replacement.

For practitioners

• How the 2014 rule still binds even though the 2026 extension adjusts the data standard timing — references in our SOPs should cite both the 2014 baseline AND the 2026 extension.

For department heads

• Legal-history audit trail when justifying current SOPs to regulators or external auditors: document both rules in the reference set.

Quick understanding check

Each question carries a hint.

Q1. How many years separate the foundational Final Rule 2014-13480 (June 2014) from the April 2026 extension announcement?

Hint: 2026 minus 2014.

Q2. What 2014 Federal Register Final Rule established the foundational electronic submission baseline for postmarketing safety reports?

Hint: FR doc cite — 2014-13480.

Q3. Does the April 2026 extension announcement replace or amend the 2014 Final Rule?

Hint: Foundational baseline vs forward-looking update distinction.

Q4. Why must compliance officers cite BOTH the 2014 baseline AND the 2026 extension when documenting the regulatory authority chain for postmarketing ICSR obligations?

Hint: Both rules together describe the current regulatory state; either alone is incomplete.

References

[7] Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements (Final Rule 2014-13480) — U.S. Food and Drug Administration (FDA), 2014-06-10; Foundational predecessor rule establishing electronic submission baseline for postmarketing safety reports

[1] Electronic Submission of Postmarketing Individual Case Safety Reports to the Food and Drug Administration Adverse Event Monitoring System Using International Council of Harmonisation E2B(R3) Data Standards; Regional Data Elements and Implementation Schedule — U.S. Food and Drug Administration (FDA), 2026-04-06; Federal Register Vol. 91, No. 65, p. 17284-17285; document 2026-06660; Docket No. FDA-2016-D-1280

[2] FDA Adverse Event Monitoring System (AEMS) Electronic Submissions [Formerly FDA Adverse Event Reporting System (FAERS)] — U.S. Food and Drug Administration (FDA), 2026-04-06; Submitting Postmarketing ICSRs; ICSR Submission Options; SRP account setup; IND-exempt BA/BE; Resources sections

[3] E2B(R3) Electronic Transmission of Individual Case Safety Reports Implementation Guide - Data Elements and Message Specification — U.S. Food and Drug Administration (FDA); Data Elements; Message Specification; Appendix on Backwards and Forwards Compatibility

[4] FDA Adverse Event Monitoring System (AEMS) - Program Overview (FDA Safety vertical) — U.S. Food and Drug Administration (FDA); AEMS scope description; broader FDA-regulated product categories consolidating under AEMS