FDA Adverse Event Monitoring System (AEMS) Electronic Submissions [Formerly FDA Adverse Event Reporting System (FAERS)]

Issuing body: U.S. Food and Drug Administration (FDA) — **Date:** 2026-04-06

Key points

- Names the two operational submission paths: ESG NextGen (E2B-capable) and Safety Reporting Portal (SRP, no-E2B-capability alternative).
- Provides the authoritative FDA contact emails: aemsesub@fda.hhs.gov (primary) and ogd-premarketsafetyreports@fda.hhs.gov (secondary, IND-exempt BA/BE).
- Names the statutory anchors inline: 21 CFR 314.80(c)(2), 21 CFR 600.80(c)(2), Section 609(a) FD&C; Act, Section 4(a) Fair Packaging and Labeling Act, MoCRA.
- Documents the eCTD + E2B(R3) coexistence within PSR submissions (eCTD descriptive portion + E2B(R3) ICSR data within same submission package).

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_01

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

- How cosmetic responsible persons under MoCRA practically integrate with the AEMS infrastructure today (operational details split across the AEMS page and the broader cosmetics-vertical guidance).
- Combination product carve-outs between CDER and CBER for drug-biologic combination products.

For practitioners

- Which submission path (ESG NextGen E2B vs SRP) is appropriate for our company size and current E2B capability — and what the cost of staying on SRP is past 1 October 2026.
- How to validate our current ICSR generation against the E2B(R3) Implementation Guide Appendix on Backwards and Forwards Compatibility.
- Whether the eCTD pipeline for PSR descriptive portions is at risk if our E2B(R3) project decommissions adjacent infrastructure.

For department heads

- Capacity planning: IT, validation, regulatory affairs, and QA teams will see workload concentration in Q3 2026; staffing and contractor backstop planning starts now.
- Vendor selection or revalidation: existing E2B vendor contracts may need amendments if vendor's R3 profile diverges from FDA Regional Implementation Guide specifics.
- Enterprise pharmacovigilance architecture: AEMS consolidates drug, biologic, and cosmetic reporting under one platform — strategic question whether to retire separate reporting silos.

Quick understanding check

Each question carries a hint.

Q1. FDA's April 2026 announcement extends the prior recommended E2B(R3) implementation period by how many months?

Hint: Page text uses the specific extension figure verbatim.

Q2. What FDA system does AEMS replace, per the subtitle on the AEMS Electronic Submissions page?

Hint: The subtitle in square brackets names the predecessor.

Q3. What two submission paths does FDA provide for sponsors transmitting postmarketing ICSRs to AEMS?

Hint: ICSR submission options section names both.

Q4. Why must eCTD format AND E2B(R3) format coexist within a single PSR submission package?

Hint: Section on Submitting PSRs Descriptive Portion explains the distinct purposes.

References

[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

[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

[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

[5] FDA Adverse Event Monitoring System (AEMS) - E2B(R3) Standards — U.S. Food and Drug Administration (FDA); FDA technical implementation specifications for E2B(R3)