MEMORANDUM

Rec'd 6/5/02

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research

DATE: May 22, 2002

FROM: Ralph B. Lillie, Director,
Office of Information Technology
CDER, HFD-070

SUBJECT: Docket 92S-0251 — Electronic Submission of Postmarketing Expedited and Periodic Individual Case Safety Reports (ICSRs only[1])

TO: Chief, Dockets Management Branch, HFA-305

Pursuant to 21 CFR Part 11.2(b) (2), and on behalf of the Center for Drug Evaluation and Research (CDER), please find attached notification of CDER's readiness to accept electronic regulatory submissions for:

Submission: Postmarketing Expedited and Periodic Individual Case Safety Reports (ICSRs only[1])

Regulatory Citation: 21 CFR 310.305(c), 314.80(c), 314.98, and 600.80(c)

Effective Date: 5/22/2002

A draft guidance document entitled, "Providing Regulatory Submissions in Electronic Format — Postmarketing Expedited Safety Reports," has been issued by FDA to aid those submitting ICSR records electronically. See 66 FR 22586, May 4, 2001. FDA is considering comments that it has received from the public on this draft guidance and will issue a final guidance on this topic shortly. This draft guidance should be used for electronic submission of both postmarketing expedited (15-day Alert reports)[2] and periodic[3] ICSR records.

---

[1] This notification applies to our intent to accept electronically postmarketing expedited and periodic ICSR records with and without ICSR attachments (e.g., published article, autopsy report/death certificate or hospital discharge summary). The descriptive information portion of postmarketing periodic adverse drug experience reports (21 CFR 3 14.80(c)(2)(ii)(a) and (c) and 600.80(c)(2)(ii)(A) and (C)) must still be submitted to FDA on paper.

[2] 21 CFR 310.305(c), 314.80(c)(1) and 600.80(c)(1)

[3] 21 CFR 314.80(c)(2)(ii)(b) and 600.80(c)(2)(ii)(B)

92S-0251

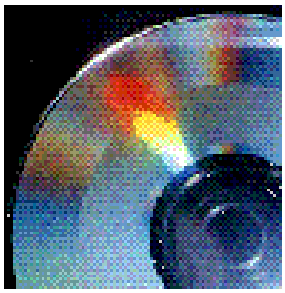
m23

With regard to submission of periodic ICSRs, for the E2B/E2BM field A.1.9 "Does this case fulfill the local criteria for an expedited report?" the field value should be "2" for the response "No." This response will indicate to FDA that the ICSR is for a postmarketing periodic adverse drug experience report.

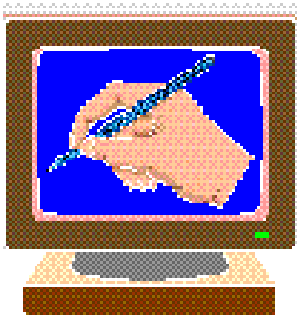
Prior to the first time that an ICSR record is to be submitted electronically to FDA, the Adverse Event Reporting System coordinator should be notified as described in the draft guidance. This applies to all ICSRs, whether expedited or periodic. If you send an expedited or periodic ICSR to FDA in an electronic format, you should not also send it to the agency on paper. We do not want duplicate reports sent to FDA by two different means.

Please add the attached notification to the official docket 92S-0251. The effect of this notice is to amend the contact information and add the ICH E2BM, ICH M2 version 2.3 DTD version 2.1 to the accepted formats.

This notice regarding Postmarketing Expedited and Periodic ICSRs supercedes the 11/29/01 notice associated with Postmarketing Expedited and Periodic ICSRs (memorandum: 15). Please remove the 11/29/2001 notice from the official docket.



21 CFR Part 11 Electronic Records; Electronic Signatures



Docket 92S-0251

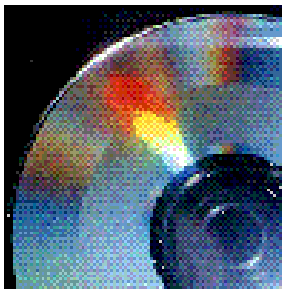
1. Receiving Unit ……:	CDER
2. Record Name ……:	Postmarket Expedited and Periodic ICSRs
3. Regulatory Citation……:	21 CFR 310.305(c), 314.80(c), 314.98 and 600.80(c).
4. Effective Date ……:	May 22, 2002

5. For information …

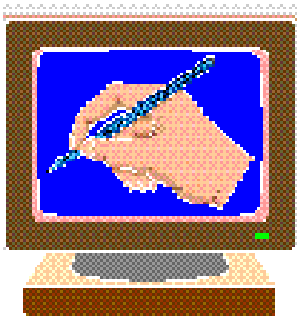
Contact:	Roger Goetsch	Phone:	301-770-9299
Fax:	301-770-6614	Email:	AERSESUB@CDER.FDA.GOV
Address:	Center for Drug Evaluation and Research (CDER) HFD-400		
	5600 Fishers Lane		
	Rockville, MD 20857		

6. Submit Electronic Records to…

Address:	Central Document Room
	Center for Drug Evaluation and Research
	5600 Fishers Lane
	Rockville, MD 20857



21 CFR Part 11 Electronic Records; Electronic Signatures



Docket 92S-0251
Page 2 of 2

7. Electronic formats …

a) SGML (in accordance with ICH E2B, ICH M2 version 2.23 DTD version 2.0 and ICH E2BM, ICH M2 version 2.3 DTD version 2.1

8. Media …

a) CD-ROM

b) Magnetic Tape

c) Floppy Disk

9. Transmission Methods …

a) FDA EDI Gateway

b) Surface Mail (media)

c)

10. An electronic copy of additional guidance describing the acceptance criteria for this electronic record may be found in…

Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports
http://www.fda.gov/cder/guidance/4153dft.pdf

Providing Regulatory Submissions in Electronic Format - General Considerations
http://www.fda.gov/cder/guidance/2867fnl.pdf