MEMORANDUM

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

DATE: May 17, 2001

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

SUBJECT: Docket 92S-0251 – Electronic Submission of Postmarketing Expedited Safety Reports – "15-day Alert Reports" (individual case safety reports (ICSRs) without attachments *)

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 Safety Reports – "15-day Alert Reports" (ICSRs without attachments *)

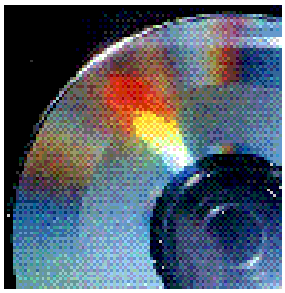
Regulatory Citation: 21 CFR 310.305(c), 314.80(c)(1), 314.98 and 600.80(c)(1)

Effective Date: 5/18/2001

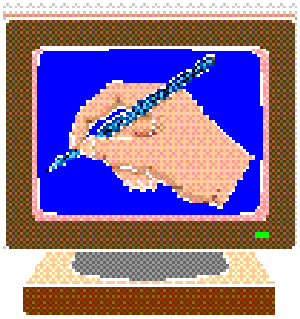
A draft guidance document entitled, "Providing Regulatory Submissions in Electronic Format – Postmarketing Expedited Safety Reports," has been issued by FDA to aid those submitting ICSR records electronically. See 66 FR 22586, May 4, 2001. FDA is soliciting public comment on this draft guidance and will issue a final guidance on this topic after consideration of the comments received. 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submitted electronically to FDA, the Adverse Event Reporting System coordinator should be notified as described in the draft guidance.

Please add the attached notification to the official docket 92S-0251.

- Note: this notification applies only to our intent to accept electronically ICSR records (15-day Alert Reports) that are unaccompanied by an attachment(s) such as a published article, autopsy report/death certificate or hospital discharge summary. ICSR records (15-day Alert reports) that are submitted with an attachment(s) must continue to be submitted on paper. Periodic adverse drug experience reports (21 CFR 314.80(c)(2) and 600.80(c)(2)) must continue to be submitted on paper.



21 CFR Part 11 Electronic Records; Electronic Signatures



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1. Receiving Unit ……:	CDER
2. Record Name ……:	Postmarketing Expedited Safety Reports *
3. Regulatory Citation……:	21 CFR 310.305(c), 314.80(c)(1), 314.98 and 600.80(c)(1)
4. Effective Date ……:	May 18, 2001

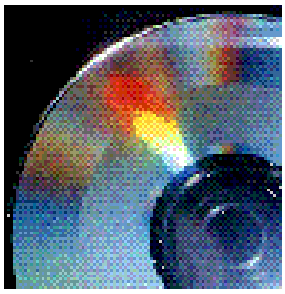
5. For information …

Contact:	Deborah Yaplee,	Phone:	301-827-3237
Fax:	301-827-5189	Email:	aersesub@cder.fda.gov
Address:	Center for Drug Evaluation and Research (CDER) HFD-400		
	5600 Fishers Lane		
	Rockville, MD 20857		

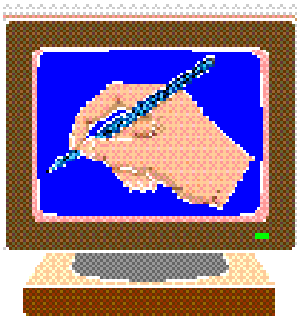
6. Submit Electronic Records to…

Address:	Central Document Room
	Center for Drug Evaluation and Research
	Food and Drug Administration
	12229 Wilkins Avenue
	Rockville, MD 20852

*** Note: ICSRs without attachments - ICSR that include attachments are not accepted electronically at this time and must continue to be submitted on paper.**



21 CFR Part 11 Electronic Records; Electronic Signatures



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7. Electronic formats …

SGML (in accordance with ICH E2B, ICH M2 version 2.23 DTD version 2.0)

8. Media …

a)	CDROM	b)	Floppy Disk	c)	Magnetic Tape

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