

MEMORANDUM

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

DATE: November 28, 2001

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<sup>1</sup>)

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<sup>1</sup>)

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

Effective Date: 11/29/2001

A draft guidance document entitled, "Providing Regulatory Submissions in Electronic Format –Postmarketing Expedited Safety Reports," has been issued by FDA to aid those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 FDA is considering comments that it has received from the public on this draft guidance and will issue a final guidance on this topic shortly. This draft guidance should be used for electronic submission of both postmarketing expedited (15-day Alert reports)<sup>2</sup> and periodic<sup>3</sup> ICSR records.

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<sup>1</sup> 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 314.80(c)(2)(ii)(a) and (c) and 600.80(c)(2)(ii)(A) and (C)) must still be submitted to FDA on paper.

<sup>2</sup> 21 CFR 310.305(c), 314.80(c)(1) and 600.80(c)(1)

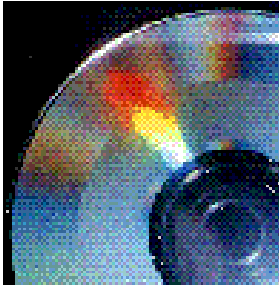
<sup>3</sup> 21 CFR 314.80(c)(2)(ii)(b) and 600.80(c)(2)(ii)(B)

With regard to submission of periodic ICSRs, for the E2B 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.

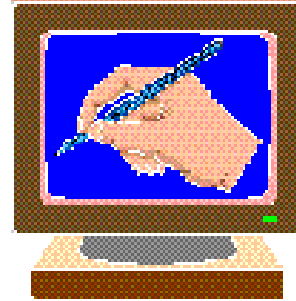
Prior to the first time that an ICSR record is to be submitted electronically to FDA, the Adverse Event Reporting System coordinator should be notified as described in the draft guidance. This applies to all ICSRs, whether expedited or periodic. If you send an expedited or periodic ICSR to FDA in an 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 postmarketing expedited and periodic individual case safety reports notice supercedes the 5/18/01 notice associated with Postmarketing expedited safety reports – “15-day Alert Reports,” please remove this notice from the official docket.



# 21 CFR Part 11 Electronic Records; Electronic Signatures



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1. Receiving Unit .....
2. Record Name .....
3. Regulatory Citation.....
4. Effective Date .....

5. For information ...

Contact:

Phone:

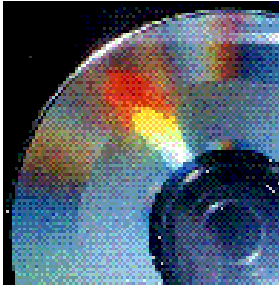
Fax:

Email:

Address:

6. Submit Electronic Records to...

Address:



**21 CFR Part 11  
Electronic Records;  
Electronic Signatures**



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7. Electronic formats ...

c)

8. Media ...

a)

b)

c)

9. Transmission Methods ...

a)

b)

c)

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