M E M O R A N D U M

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

DATE: January 29, 1999

FROM: David Isom, Director
Office of Information Technology
CDER, HFD-070

SUBJECT: Docket 925-0251- Update Transmittal

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: New Drug Application Submissions
Regulatory Citation: 21 CFR314 (50)
Effective Date: 2/1 /99

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

The New Drug Application notice supersedes the 9/25/97 notices associated with Case Report Tabulations and Case Report Forms, please remove these notices from the official docket.

cc: HFD-007, Thomas C. Kuchenberg
HFD-006, Nancy E. Derr

925-0251

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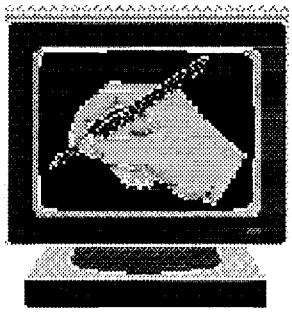
Rec'd
1-29-99
JB

21 CFR Part 11 Electronic Records; Electronic Signatures



Docket 92S-0251

1. Receiving Unit .....:	Center for Drug Evaluation and Research
2. Record Name .....:	New Drug Applications
3. Regulatory Citation.....:	21 CFR 314(50)
4. Effective Date .....:	01-FEB-1999

5. For information ...

Contact:	Ken Edmunds	Phone:	301-827-3276
Fax:	301-594-6183	Email:	ESUB@CDER.FDA.GOV
Address:	CDER/OIT HFD-73		
	5600 Fishers Lane		
	Rockville, MD 20857		

6. Submit Electronic Records to...

Address:	Central Document Room
	12229 Wilkens Avenue
	Rockville, MD 20852

92S-0251

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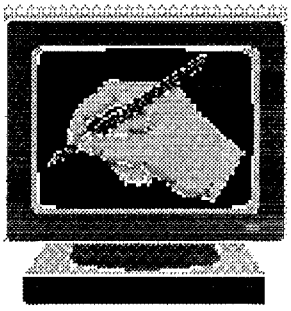
21 CFR Part 11 Electronic Records; Electronic Signatures



Case Report Tabulations (cont) ...

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7. Electronic formats ...

a) PDF | b) SAS Transport | c)

8. Media ...

a) CDROM | b) Magnetic Tape | c)

9. Transmission Methods ...

a) Surface Mail | b) | 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 General Considerations
http://www.fda.gov/cder/guidance/2867fnl.pdf

Providing Regulatory Submissions in Electronic Format — NDAs
http://www.fda.gov/cder/guidance/2353fnl.pdf