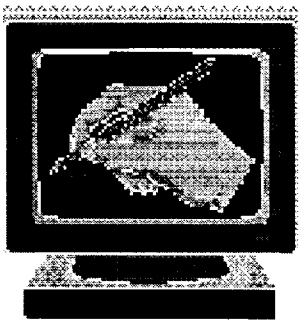
21 CFR Part 11 Electronic Records; Electronic Signatures



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1. Receiving Unit .....: Center for Drug Evaluation and Research
2. Record Name .....: Case Report Forms
3. Regulatory Citation.....: 21 CFR 314(50)(f)(2)
4. Effective Date .....: 25-SEP-1997

5. For information ...

Contact: Ken Edmunds
Phone: 301-827-3276
Fax: 301-594-6183
Email: EDMUNDS@CDER.FDA.GOV
Address: FDA/CDER/Office of Information Technology HFD-070
5600 Fishers Lane
Rockville, MD 20857

6. Submit Electronic Records to...

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

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M2

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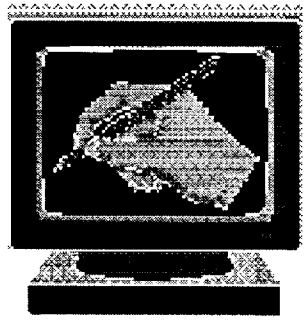
Electronic Records; Electronic Signatures



Case Report Forms (cont) ...

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7. Electronic formats ...

a) PDF b) 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...

http://www.fda.gov/cder/guidance/1219fnl.pdf