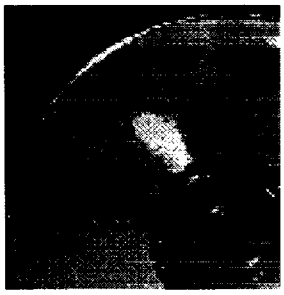
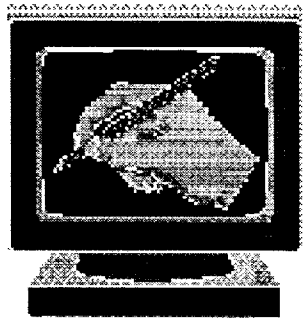


21 CFR Part 11 Electronic Records; Electronic Signatures



Docket 92S-0251

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

5. For information ...

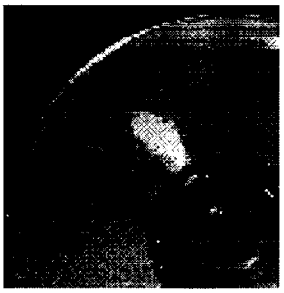
Contact: Ken Edmunds
Phone: 301-827-3276
Fax: 301-594-6183
Email: EDMUNDS@CDER.FDA.GOV
Address: FDA/CDER/Office of Information Technology HFD-070
5600 Fishers Lane
Rockville, MD 20857

6. Submit Electronic Records to...

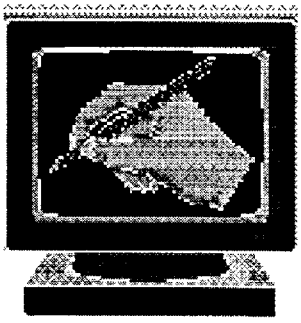
Address: Central Document Room
12229 Wilkens Avenue
Rockville, MD 20852

92S-0251

M3



21 CFR Part 11 Electronic Records; Electronic Signatures



Case Report Tabulations (cont) ...

Docket 92S-0251
Page 2 of 2

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