

MEMORANDUM

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

DATE: August 8, 2003

FROM: Michael B. Fauntleroy
Director, Electronic Submissions
Office of the Director
CBER, HFM-26

SUBJECT: Docket 92S-0251 - Transmittal

TO: Chief, Dockets Management Branch, HFA-305

Pursuant to 21 CFR Part 11.2(b) (2), and on behalf of the Center for Biologics Evaluation and Research (CBER), please find attached notification of CBER's readiness to accept electronic regulatory submissions for:

Submission: Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) (Form FDA 3356)

Regulatory Citation: 21 CFR 1271.22

Effective Date: August 08, 2003

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

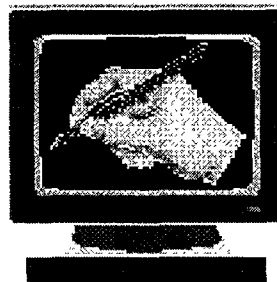
In addition to accepting by mail, beginning August 08, 2003, CBER will accept electronically the Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) (Form FDA 2830). Instructions for completing the electronic format are available at <http://www.fda.gov/cber/tissue/tisreg.htm>.

92S-0251

m26



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



Docket 92S-0251

Page 1 of 2

1. Receiving Unit: **Center for Biologics Evaluation and Research**
2. Record Name: **Establishment Registration and Listing for Human Cells**
3. Regulatory Citation.....: **21 CFR 1271.22**
4. Effective Date: **08-AUG-2003**

5. For information ...

Contact: **Rosemarie Wiseman** Phone: **(301) 827-6176**

Fax: **(301) 827-2844** Email: **tissuereg@cber.fda.gov**

Address: **FDA/Center for Biologics Evaluation and Research/HFM-775**

1401 Rockville Pike

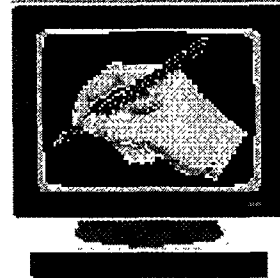
Rockville, MD 20852-1448

6. Submit Electronic Records to...

Address: **<http://www.fda.gov/cber/tissue/tisreg.htm>**



**21 CFR Part 11
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Docket 92S-0251
Page 2 of 2

7. Electronic formats ...

a) **HTML/Cold Fusion**

b)

c)

8. Media ...

a) **Internet browser**

b)

c)

9. Transmission Methods ...

a) **SSL**

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/cber/tissue/tisreginstr.htm>