ABBOTT

Corporate Regulatory and Quality Science

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May 4, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane,
Rockville, MD 20852

Ref: **Docket No. 97N-484P** – 21 CFR Part 1271
"Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement" Proposed Rule.

Abbott Laboratories is pleased to provide the following comments on the Proposed Rule "Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement" published in the Federal Register on Jan 8, 2001.

1. **Section 1271.180 states, "Any deviation from a procedure shall be authorized in advance by a responsible person, recorded, and justified."**

   It is unreasonable to expect that all deviations be authorized in advance. Infrequent occurrences due to unplanned events may result in a deviation without prior authorization; however, systems would be implemented to follow through with investigations and appropriate corrective and preventive actions in order to prevent the recurrence of the event.

2. **Section 1271.200 (a) states, "Any automated, mechanical, electronic, computer, or other equipment used for inspection, measuring, and testing shall be capable of producing valid results."**

   Clarification of "valid results" is needed. Valid results may be obtained through appropriate validation and/or calibration of equipment.

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3. **Section 1271.200 (e) states, "Records of recent maintenance, cleaning, sanitizing, calibration, and other activities shall be available at each piece of equipment."**

   Manufacturing equipment may be located in an environment constructed and maintained in such a manner that minimizes non-viable and viable particulate (for example, a class 10,000 clean room). In such cases, the placement of records aeach piece of equipment may be impractical. Equipment records should, therefore, be stored in a readily retrievable location.

4. **Section 1271.265 (d) states, "Packaging and shipping containers shall be designed, validated and constructed to ensure product function and integrity..."**

   In lieu of validation for some packaging containers, integrity testing of each container may be appropriate for ensuring product function and integrity.

We thank the Agency for your consideration of our comments. Should you have any questions, please contact Carla Montes at 847-937-4597 or by FAX at 847-938-5878.

Sincerely,

D Sporn by R Poska

Douglas Sporn
Divisional Vice-President
Corporate Regulatory Affairs

cc. Diane Campen, SPD-RA
Richard Poska, CR&QS

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