MIDSOUTH EYEBANK
FOR SIGHT RESTORATION

8309 '01 MAY -8 A10:32

May 7, 2001

Jane Henney, M.D., Commissioner
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

RE: Comments on Docket No. 97N-484P: Current Good Tissue practice for Manufacturers of Cellular and Tissue-Based Products, Inspection and Enforcement, Proposed Rule; 21 CFR Federal Register Part 1271; January 8, 2001.

Dear Dr. Henney:

The Mid South Eye Bank (MSEB) would like to comment on this proposed FDA regulation. In some cases, the rules are burdensome and unnecessary for eye banks and impose an unreasonably difficult standard which no one can truly meet. They will not add anything to tissue quality but will add a significant paperwork burden to an already overburdened health care activity.

MSEB was founded in 1945 and, in 2000, procured 650 corneas or whole eyes annually and supported 331 transplants by local, national and international physicians. Our FDA visit this year resulted in a "clean" inspection with no deficiencies. While we appreciate the FDA visits as a measure of our success, we feel this proposed rule, while well meaning, requires procedures which are unduly burdensome for small eye banks without significant financial resources. Thank you for the opportunity to comment on the rule.

Section § 1271.150, et al: The language in this section is sufficiently vague to provide for interpretation by individual inspectors regarding the extent to which to apply the regulation. For example, must we inspect Federal Express, UPS or the Postal Service to insure that they comply in all respects to FDA regulations while shipping corneas for other than local transplant?

Also, it is unrealistic to expect an eye banker to have the expertise to "inspect/validate" a blood testing laboratory or Bausch & Lomb (which manufactures the OptisolGS corneal preservation media). It is likely these facilities are already inspected by FDA (not Fed Ex, of course) and we already obtain CLIA and other verification from the labs. In most cases, these installations are remote from the eye bank and can only be visited at considerable expense.

A reasonable alternative is for a truly qualified person to inspect the lab or other installation (i.e., a chemist for Bausch & Lomb) and report back through EBAA for ***all eye banks in the system.*** This seems to me to be a reasonable alternative to each of the 90+ eye banks taking this costly trip to inspect these facilities and "grade" their activities.

97N-484P C20

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RE: **Comments on Docket No. 97N-484P: Current Good Tissue practice for Manufacturers of Cellular and Tissue-Based Products, Inspection and Enforcement, Proposed Rule; 21 CFR Federal Register Part 1271; January 8, 2001.**

Section § 1271.225 & .230 "Validation" is not a process which comes easily in eye banking. Mechanical devices are used in the processing of tissue (i.e., slit lamps, specular microscopes and, in some cases, Laminar flow hoods) these are validated annually by inspection/certification process either by in-house personnel or an independent contractor. Technical Directors and Certified Technicians who grade tissue and evaluate its efficacy are already trained to death and I do not understand how much more we can do to improve this process. Perhaps clarification of exactly what procedures are expected of the eye banks and their staffs might help us on this rule.

Section § 1271.320 The definition provided in this paragraph is too vague and unduly penalizes an eye bank for what may, in fact, be operating room sterility problems or poor surgical techniques. It leaves the eye bank open to baseless accusations by recipients, family members or physicians for the failure of a graft which may have been due to other causes. This section should give the eye bank an opportunity to "filter out" unfounded complaints.

We feel that better language for this Section would be to include only "that tissue relating to communicable disease transmission or graft failure".

Section § 1271.350 The 15 day reporting period is arbitrary and, we feel, does not give sufficient time to fully investigate an alleged complaint. We would urge the FDA to provide a more reasonable 30 day period for this reporting. Also, if a complaint investigation results in an outcome which points to a cause other than a failure of the eye bank's good tissue practice, are we required to still report these results as well?

Finally, it is my fervent hope that the Eye Banks, the Eye Banks Association of America and the FDA can be partners in this process and apply these regulations in a spirit of reasonableness and cooperation. You can be assured that our eye bank currently provides a quality cornea for transplant and we are amenable to any reasonable suggestions or constructive criticism which will allow us to improve our quality or do a better job in that regard.

We have difficulty with regulations which add to the paperwork burden (which this rule most assuredly does) or is unduly costly (esp. the validation provisions). We urge you to be reasonable with us and you will find us positively responsive.

Respectfully submitted,

Lee Williams

Lee Williams, Executive Director

LW:jh

CC: EBAA

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