

# American Association of Tissue Banks

*The leader in support of quality, safety and availability of cells and tissue*

24th Annual Meeting, September 9-12, 2000, Sheraton Bal Harbour, Florida

9714 '01 FEB -6 A9:53

January 31, 2001

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Dockets Management Branch (HFA-305)

Food and Drug Administration

5630 Fishers Lane

Room 1061

Rockville, MD 20852

Ms. Wendy Taylor

Desk Officer for FDA

Office of Information and Regulatory Affairs

Office of Management and Budget

New Executive Office Building

725 17<sup>th</sup> Street, N.W.

Washington, DC 20503

**Re:** REQUEST FOR EXTENSION OF COMMENT PERIOD

***Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement (21 CFR Part 1271)***

**Docket No. 97N-484P**

Dear Madams/Sirs and Ms. Taylor:

I am writing on behalf of the American Association of Tissue Banks (AATB) to request a 60-day extension of the comment period on the information collection provisions in the above-caption proposed rule.

The Food and Drug Administration (FDA) published this proposed rule in the January 8, 2001, edition of the *Federal Register*. The proposed rule contains two comment periods: written comments on the proposed rule itself are due by May 8, but written comments on the information collection provisions in the proposed rule must be submitted by February 7. The AATB hereby requests a 60-day extension of the February 7 comment period to on or about April 2, 2001.

97N-484P

EXT,

Dockets Management Branch (HFA-305)

Food and Drug Administration

Ms. Wendy Taylor

Office of Management and Budget

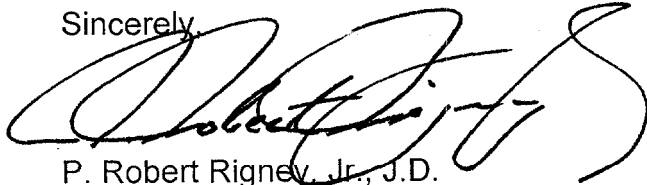
January 31, 2001

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The reason for this request is that comments on the information collection provisions in the proposed rule could not feasibly be submitted within the 30-day time period permitted. The proposed rule contains at least 12 separate requests for information. Most of the data needed to respond are not readily available, and thoughtful consideration and research are required in order to provide meaningful information. It has taken the Agency several years to craft this proposed rule. Sound public policy dictates that more than 30 days are necessary to respond to requests for information that the Agency itself has been unable to gather over several years.

I thank you for your time and immediate consideration of this request. If you have any questions, please do not hesitate to contact me. I look forward to hearing from you at your earliest possible convenience.

Sincerely,

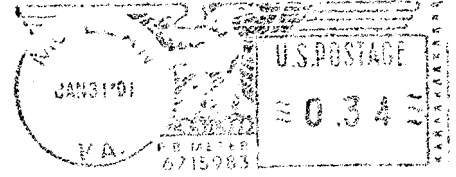
A handwritten signature in black ink, appearing to read "P. Robert Rigney, Jr.", written in a cursive style.

P. Robert Rigney, Jr., J.D.

Chief Executive Officer

PRRJr/dbn

**Association of Tissue Banks**  
7 Road, Suite 220-A  
Pine Bluff, AR 71601



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