

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210, 211, 820, and 1271

[Docket No. 97N-484S]

Suitability Determination for Donors of Human Cellular and Tissue-Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

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| Display Date | 4-17-00 |
| Publication Date | 4-18-00 |
| Certifier | SARRE |

SUMMARY: The Food and Drug Administration (FDA) is reopening for 90 days the comment period for the proposed rule concerning suitability determinations for donors of human cellular and tissue-based products. The proposed rule was published in the **Federal Register** of September 30, 1999 (64 FR 52696). This action is being taken in response to requests for an extension to allow interested parties, including State and local officials, additional time for review and to submit comments.

DATES: Submit written comments on the proposed rule by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 30, 1999 (64 FR 52696), FDA published a proposed rule to require manufacturers of human cellular and tissue-based products to screen and test the donors of cells and tissue used in those products for risk factors

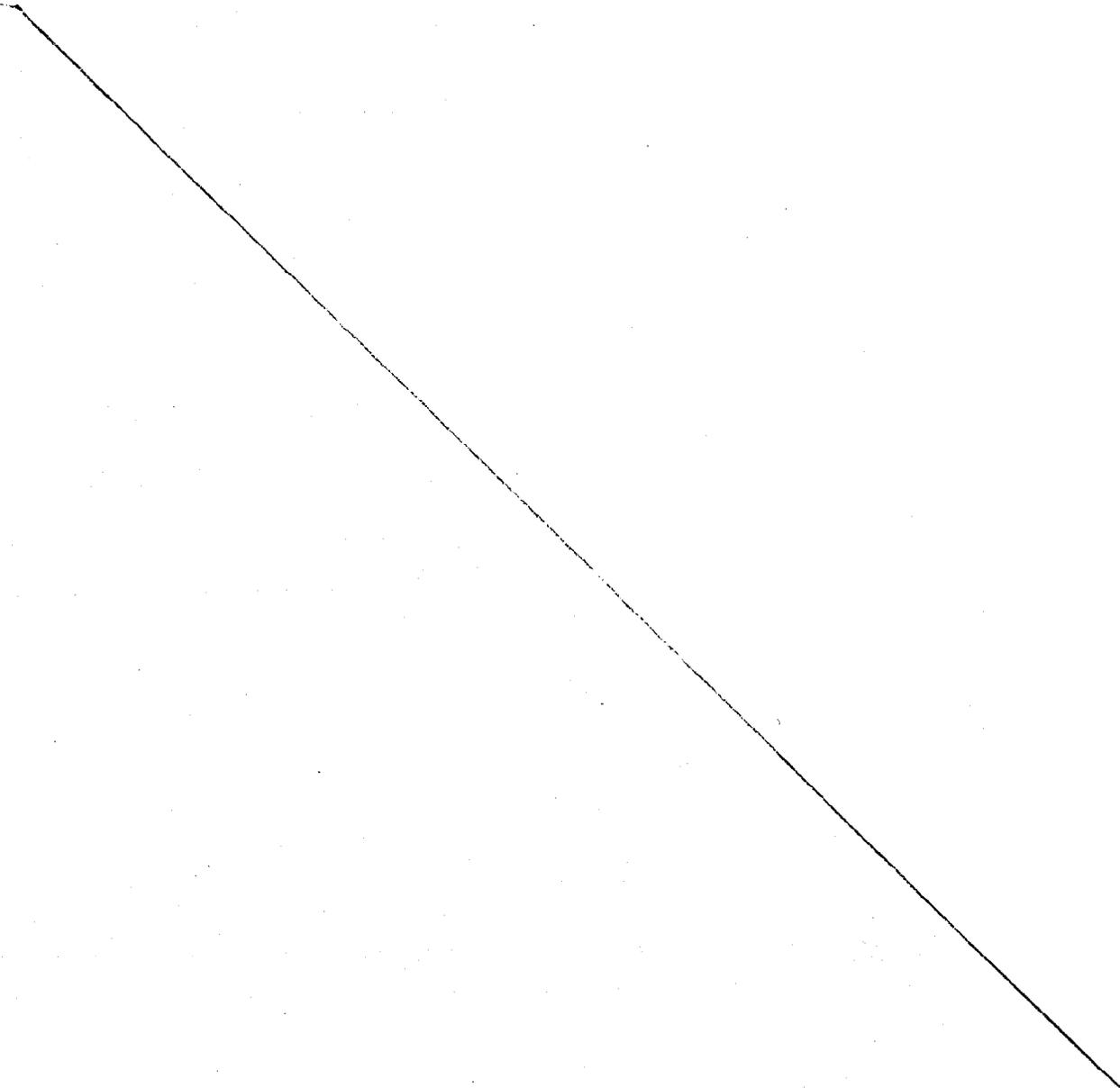
for and clinical evidence of relevant communicable disease agents and diseases. As part of that regulatory action, the agency proposed to amend the current good manufacturing practice regulations that apply to human cellular and tissue-based products regulated as drugs, medical devices, and/or biological products to incorporate the new donor-suitability procedures into existing good manufacturing practice regulations. Interested persons were given until December 29, 1999, to submit written comments on the proposed rule.

On November 19, 1999, a comment was submitted to the docket by a professional association requesting a 60-day extension of the comment period on the proposed rule. The comment requests additional time to allow an ad hoc group of experts assembled by the organization to complete the collection and analysis of scientific data on transmissible spongiform encephalopathies and Creutzfeld-Jakob Disease. The association also noted the recent publication of the proposed rule entitled "Standards for Privacy of Individually Identifiable Health Information" by the Department of Health and Human Services (64 FR 59918, November 3, 1999), and requested an opportunity to evaluate the potential impact of that proposed rule in relation to the September 30, 1999, proposed rule. On December 1, 1999, a second comment requested an extension to at least January 31, 2000.

In addition, FDA has learned that the State of California and other jurisdictions have enacted legislation and issued regulations governing tissue donor suitability. Because those laws might conflict with provisions in the September 30, 1999, proposed rule, FDA has invited State officials to participate in this rulemaking. The agency would appreciate comment on: (1) The need for uniform national standards for donor suitability determinations to prevent communicable disease transmission through human cellular and tissue-based products, (2) the scope of such proposed national requirements and their impact upon State laws, (3) FDA's proposal not to preempt State laws on legislative consent for cornea transplants, and (4) any issues raised by this proposed rule possibly affecting State laws and authorities. To allow sufficient time for this to occur, as well

as to allow all interested persons additional time to evaluate information and submit meaningful comments, the agency is reopening the comment period for 90 days.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the proposed rule by *[insert date 90 days after date of publication in the Federal Register]*. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets



in the heading of this document. The proposed rule and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4-10-00
April 10, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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