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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207,807, and 1271

[Docket No. 97N-484R]

RIN 0910-AB05

Establishment Registration and Listing for Manufacturers of Human Cellular and TissueBased Products

AGENCY: Food and Drug Administration, HHS.

ACTION: <sup>Proposed rule</sup> ~~Notice~~; reopening of comment period. *per Vince JOFK*

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**SUMMARY:** The Food and Drug Administration (FDA) is reopening the comment period for the proposed rule concerning establishment registration and listing for manufacturers of human cellular and tissue-based products that was published in the **Federal Register** of May 14, 1998 (63 FR 26744). FDA is taking this action in response to a request for an extension and to allow interested parties additional time for review and to submit comments.

**DATES:** Submit written comments on the proposed rule by (insert *date 60 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.

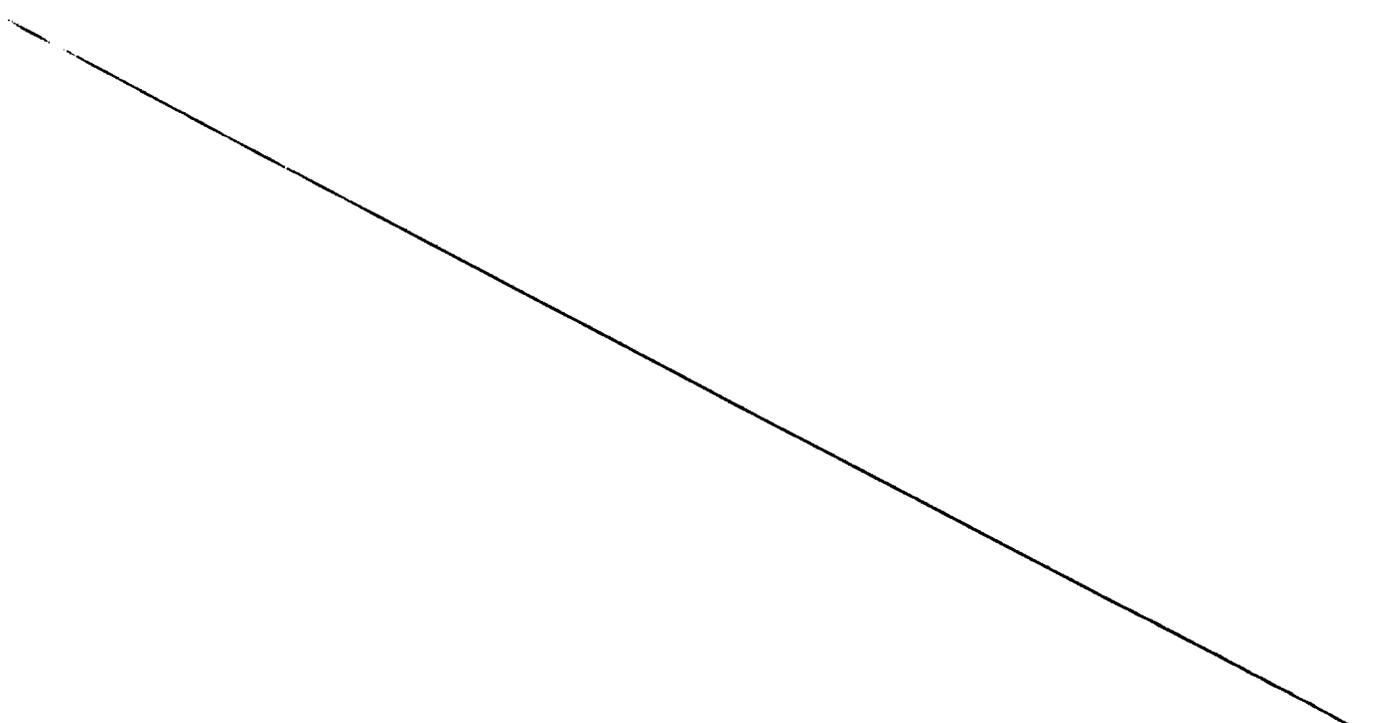
**FOR FURTHER INFORMATION CONTACT:** Paula S. McKeever, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 14, 1998 (63 FR 26744), FDA published a proposed rule to require manufacturers of certain human cellular and tissue-based

products to register with the agency and list their products. In addition, the agency proposed to amend the registration and listing regulations that currently apply to human cellular and tissue-based products regulated as drugs, devices, and/or biological products. Interested persons were given until August 12, 1998, to submit written comments on the proposed rule.

On August 6, 1998, a comment was submitted to the docket requesting that the agency extend the comment period on the proposed rule 60 days. The comment noted that certain information relevant to the rulemaking was not included in the public docket. Because the docket was scheduled to close on August 12, 1998, there was insufficient time to prepare and submit a letter of extension to the docket. However, the agency agrees that an additional period will provide time for interested parties to review the proposed rule and information now placed in the public docket and submit written comments. Therefore, the agency is reopening the comment period for an additional 60 days, until *(insert date 60 days after date of publication in the **Federal Register**)*.

Interested persons may, on or before *(insert date 60 days after date of publication in the **Federal Register**)* submit to the Dockets Management Branch (address above) written comments on the proposed rule. 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 1, 1998  
December 1, 1998



William K. Hubbard  
Associate Commissioner for Policy Coordination

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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