

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. 2006N-0051]

Health Resources and Services Administration

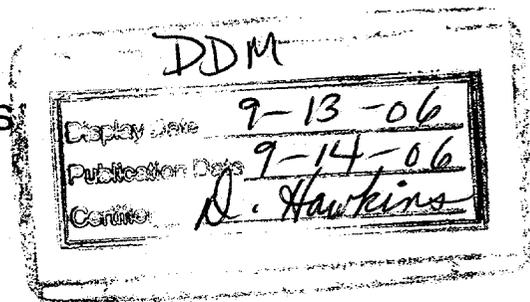
42 CFR Part 121

Blood Vessels Recovered With Organs and Intended for Use in Organ Transplantation; Withdrawal

AGENCIES: Food and Drug Administration, Health Resources and Services Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Health Resources and Services Administration (HRSA) and the Food and Drug Administration (FDA) published in the **Federal Register** of May 12, 2006 (71 FR 27606), a direct final rule to amend the regulations to consider as part of an organ those blood vessels recovered with the organ that are intended for use in organ transplantation; and to exclude such blood vessels from the definition of human cells, tissues, and cellular and tissue-based products. The comment period closed July 26, 2006. HRSA and FDA are withdrawing the direct final rule because FDA received significant adverse comment. The agencies will consider the comments received under our usual procedures for notice and comment in connection with the notice of proposed rulemaking that was published as a companion to the direct final rule (71 FR 27649).



DATES: The direct final rule published on May 12, 2006 (71 FR 27606), is withdrawn effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT:

For information regarding FDA's rule: Pamela Pope, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

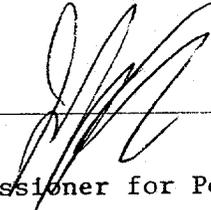
For information regarding HRSA's rule: Jim Burdick, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, room 12C-06, Rockville, MD 20857, 301-443-7577.

SUPPLEMENTARY INFORMATION: HRSA and FDA published a direct final rule in the **Federal Register** of May 12, 2006 (71 FR 27606), to amend the regulations to consider as part of an organ those blood vessels recovered with the organ that are intended for use in organ transplantation (HRSA regulation); and to exclude such blood vessels from the definition of human cells, tissues, and cellular and tissue-based products (FDA regulation).

HRSA and FDA received significant adverse comment in response to the direct final rule. Therefore, the direct final rule is being withdrawn. HRSA and FDA intend to finalize the proposed rule after considering comments.

AUTHORITY: Therefore, under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs and to the Administrator, Health Resources and Services Administration, the direct final rule published on May 12, 2006 (71 FR 27606), is withdrawn.

Dated: 9/6/06
September 6, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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Dawn P. Hawkins