Related Information

(h) France AD No. F–2005–146, dated August 17, 2005, also pertains to the subject of this AD.

(i) Contact Tracy Murphy, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7172; fax (781) 238–7170, for more information about this AD.

Material Incorporated by Reference

(j) You must use Microturbo Alert Service Bulletin No. 095–49A11, Edition 2, dated October 7, 2005 to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Microturbo SA; Technical Publications Department; 8 Chemin du pont de Rupe, BP 62089; 31019 Toulouse Cedex 2, France; telephone 33 0 5 61 37 55 00; fax 33 0 5 61 70 74 45.

(3) You may review copies at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on March 2, 2007.

Robert J. Ganley,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E7–4140 Filed 3–9–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. 2006N–0051]

RIN 0910–AF65

Health Resources and Services Administration

42 CFR Part 121

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

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

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) and the Health Resources and Services Administration (HRSA) are amending their regulations to include 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, or cellular or tissue-based products (HCT/Ps) (FDA regulation). The purpose of this final rule is to amend the regulations so that blood vessels recovered with organs and intended for use in organ transplantation, and labeled as such, are governed by the regulations pertaining to organs. The regulation of other recovered blood vessels remains unchanged. We (HRSA and FDA) believe that this change will eliminate the burden resulting from an organ procurement organization's efforts to comply with both FDA and HRSA rules with respect to blood vessels (FDA jurisdiction) and organs (HRSA jurisdiction).

DATES: This rule is effective on April 11, 2007.

FOR FURTHER INFORMATION CONTACT:

For information regarding FDA's rule: Denise Sánchez, 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 (HRSA), 5600 Fishers Lane, rm. 12C–06, Rockville, MD 20857, 301–443–7577.

SUPPLEMENTARY INFORMATION:

I. Introduction

HRSA oversees transplantation of organs through the Organ Procurement and Transplantation Network (OPTN), which sets policies related to the procurement, transplantation, and allocation of human organs (see 42 CFR part 121). FDA currently regulates blood vessels. However, FDA does not regulate vascularized human organs (see 21 CFR 1270.3(j)(4) and 1271.3(d)(1)). FDA's jurisdiction over blood vessels intended for use in organ transplantation overlaps with HRSA's oversight of the OPTN.

There is a routine practice of recovering blood vessels intended for use in organ transplantation during organ procurement and using such blood vessels to connect donor organ and recipient vessels. Blood vessels intended for use in organ transplantation are recovered with human organs by Organ Procurement Organizations (OPOs) and stored for use at transplant centers. Both OPOs and transplant centers are already subject to HRSA oversight because of their organ procurement and transplantation activities. The application of both HRSA and FDA regulatory requirements to these facilities in relation to organs and blood vessels procured for use in organ transplantation is not supported by a need for such dual oversight. In order to avoid the duplication of efforts and reduce the burden on affected facilities, this final rule transfers from FDA to HRSA jurisdiction over blood vessels intended and labeled for use in organ transplantation. This final rule does not affect the regulation of blood vessels intended for transplantation that do not involve organ transplantation. Jurisdiction over such blood vessels remains with FDA.

Under this final rule, blood vessels labeled and intended solely for use in organ transplantation will be subject to HRSA requirements in 42 CFR part 121 and any enforceable OPTN policies established under 42 CFR part 121. To be regulated under HRSA requirements, such blood vessels intended for use in organ transplantation must be labeled ''For use in organ transplantation only.'' However, they are not required to be attached to the organ(s), transplanted simultaneously with such organ(s) to the same recipient, or transplanted with the organ(s) from the same donor. For example, occasionally blood vessels not used immediately for the transplantation of a donated organ are stored for a number of days and subsequently used to modify the organ transplant in the same recipient or to accomplish transplantation in the

recipient of an organ from a different donor. Such blood vessels intended and labeled for use in organ transplantation may be used in these ways when the use is consistent with HRSA requirements.

II. Background

In the **Federal Register** of May 12, 2006, we published a direct final rule and a companion proposed rule (71 FR 27606 and 27649, respectively) to revise HRSA's definition of ''organ'' to include blood vessels recovered from an organ donor during the same recovery procedure of such organ(s) and intended and labeled for use in organ transplantation; and to exclude such blood vessels from FDA's definition of human cells, tissues, or cellular or tissue-based products (HCT/Ps) (21 CFR 1271.3(d)). The direct final rule amended the regulations so that blood vessels intended and labeled for use in organ transplantation were under the same regulatory scheme as organs, thereby making blood vessels intended and labeled for use in organ transplantation readily available to meet organ transplant needs. Such direct final rule would become effective unless we received significant adverse comment. We published a companion proposed rule to provide a procedural framework within which the rule could be finalized in the event we received any significant adverse comments regarding the direct final rule, and the direct final rule had to be withdrawn.

We received comments from health care professionals and a nonprofit organization. Among the comments received, one comment fully supported the rulemaking. Another comment concerned the use and tracking of blood vessels recovered from a deceased organ donor but not transplanted with the recovered organ, and questioned the transfer of regulatory responsibility for such blood vessels from FDA to HRSA. Another comment suggested that the rulemaking distinguish between organ transplant recipients based on the type of their organ donor (living, nonrelated; living, related; or deceased) and use these distinctions to define who may receive the blood vessels addressed in the rulemaking. The comments received and our responses to the comments are discussed in section IV of this document. Because we received significant adverse comment in response to the rulemaking, we published a notice in the **Federal Register** of September 14, 2006 (71 FR 54198), withdrawing the direct final rule.

III. Highlights of the Final Rule

To transfer from FDA to HRSA jurisdiction over blood vessels intended for use in organ transplantation, the final rule amends 21 CFR 1271.3(d), 42 CFR 121.2, and 42 CFR 121.7 as follows:

A. 21 CFR 1271.3(d)

21 CFR 1271.3(d) defines HCT/Ps as ''articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.'' In the definition, we also exclude certain articles from the definition of HCT/Ps. This final rule adds § 1271.3(d)(8), excluding from the definition of HCT/Ps blood vessels intended for use in organ transplantation. The rule excludes such blood vessels intended for use in organ transplantation only when they are labeled as ''For use in organ transplantation only,'' to distinguish such vessels from blood vessels not intended for use in organ transplantation. By labeling such blood vessels ''For use in organ transplantation only,'' we expect that they will not be used for other purposes. Under the final rule, blood vessels intended for other uses remain subject to 21 CFR part 1271.

B. 42 CFR 121.2

Under 42 CFR 121.2, ''Organ'' means a human kidney, liver, heart, lung, or pancreas. This final rule adds to that definition ''Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this Part if the vessels are intended for use in organ transplantation and labeled 'For use in organ transplantation only'.'' Blood vessels intended for use in organ transplantation are required to be in compliance with HRSA provisions for donor screening and testing. The labeling provision is required in order for such blood vessels to fall under this regulatory program. Any OPTN labeling policies, whether voluntary or enforceable, supplement this requirement.

C. 42 CFR 121.7

In 42 CFR 121.7, we are redesignating paragraph (e) as paragraph (f), and adding a new paragraph (e). Under 42 CFR 121.7(e), a blood vessel intended for use in organ transplantation is subject to the allocation requirements under 42 CFR part 121 and enforceable OPTN policies pertaining to the organ with which the blood vessel is procured. These provisions apply until the transplant center receiving the organ determines that the blood vessel is not needed for the transplantation of that organ. This allocation priority assures that vessels that may be necessary for the immediate transplantation of the organs with which they are recovered are made available for that use prior to being diverted to other organ transplant uses.

IV. Comments on the Proposed Rule and HRSA and FDA Responses

(Comment 1) One comment supported the proposed rule. The comment stated that the Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS) Board of Directors has approved a policy to provide guidance for the recovery, use, and storage of deceased donor vascular allografts. The comment also stated that the OPTN/UNOS policy does not result in undue burden to the transplant community and is consistent with the provisions of the proposed rule.

(Response) We appreciate the supportive comment. One of our reasons for the proposed rule is to eliminate the burden of dual oversight, by FDA and HRSA, of those blood vessels used in organ transplantation. The policy discussed in the comment is OPTN/UNOS Policy 5.7.[1] OPTN/UNOS Policy 5.7 addresses practices for blood vessel recovery, storage, and transplant by transplant centers and OPOs. The policy will only be implemented once this final rule goes into effect.

(Comment 2) One comment stated that patients would be better protected under the existing regulatory scheme. The comment questioned the safety of transplanting blood vessels recovered from a deceased organ donor into third party recipients who received organs from other donors. The comment explained that use of blood vessels in these recipients poses disease transmission and human leukocyte antigen (HLA) sensitization risks that jeopardize patient safety. The comment also stated that the OPTN and organ transplant programs lack adequate tracking and traceability mechanisms for such blood vessels.

(Response) We acknowledge that the use of blood vessels poses disease transmission and HLA sensitization risks in third party recipients. The intent of this rule is to facilitate the successful completion of life-saving organ transplants in medical procedures

[1] See *http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_17.pdf.* (FDA and HRSA have verified the Web site address, but the agencies are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

where the vasculature of the donated organ is inadequate, or to salvage a graft that would otherwise be lost. It is up to the organ transplant surgeon to assess the risks and benefits of, and alternatives to, using a particular vessel to accomplish or modify an organ transplant. Moreover, the risks of disease transmission and HLA sensitization would apply even if FDA retained jurisdiction over these blood vessels as HCT/Ps. FDA regulations, like HRSA policies, reduce, but cannot entirely eliminate, the risk of disease transmission, and FDA tissue regulations do not address HLA sensitization. In addition, the OPTN has long-established mechanisms for tracking of organs from the donor to the recipient, which require the reporting of transplant outcomes. HRSA intends to monitor the use and outcomes of these vessels used in organ transplantation, and to work with the OPTN to modify policies governing their use as needed.

(Comment 3) One comment suggested that the rulemaking should distinguish between organ recipients based on the type of their organ donor (living, nonrelated; living, related; or deceased) and use these distinctions to define the types of transplant recipients who may receive these vessels for organ transplant use. The comment asked whether a surgeon may use vessels from a deceased donor to repair a thrombosed renal artery in the recipient of a living donor kidney.

(Response) We decline to make these suggested changes to the rulemaking. The language in 42 CFR 121.7(e) establishes a priority allocation for use of vessels with organs from the same donor. If vessels are not needed for this use, the rule does not preclude vessels recovered from deceased donors and labeled ''For use in organ transplantation only'' from being transplanted into recipients of organs from living donors, either to perform the initial transplant of the organ or to later modify the organ transplant. The situation described in the comment would be an example of the use of such vessels to modify a transplant.

V. Legal Authority

We are issuing these regulations under the authority of the National Organ Transplant Act as amended (NOTA) and section 361 of the Public Health Service Act (the PHS Act). NOTA authorizes HRSA, by delegation from the Secretary, to issue regulations governing the operation of the OPTN. NOTA, as amended, also authorizes the Secretary to define human organs to be covered by the OPTN. Section 374 of the PHS Act specifically states, ''[t]he term 'organ' means the human kidney, liver, heart, lung, pancreas, *and any other human organ (other than corneas and eyes) specified by the Secretary by regulation.** * *.'' (42 U.S.C. § 274b(d)(2)) (emphasis supplied). Accordingly, HRSA is issuing this regulation to modify the definition of ''organ,'' and to make blood vessels labeled and intended for use in the transplantation of organs subject to regulations governing the operation of the OPTN. Extending the definition of organs governed by HRSA in 42 CFR 121.2 to add blood vessels recovered with organs that are intended for use in organ transplantation, and labeled as such, furthers the Secretary's charge under NOTA.

Under the authority of section 361 of the PHS Act delegated to the Commissioner of FDA, the Department of Health and Human Services may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. This modification of FDA's existing regulation reflects FDA's re-evaluation of the level of regulation that is necessary to prevent disease transmission involving blood vessels intended for use in organ transplantation.

VI. Analysis of Impacts

FDA and HRSA have examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agencies believe that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the agencies do not expect that the transfer from FDA to HRSA of jurisdiction over the blood vessels described in the rule will result in substantial changes in the way transplant hospitals and OPOs procure, store, and transplant such blood vessels, FDA and HRSA certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. The Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VIII. Environmental Impact

FDA and HRSA have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Federalism

FDA and HRSA have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA and HRSA have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA and HRSA have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. Effective Date

This final rule is effective on April 11, 2007.

List of Subjects

21 CFR Part 1271

Biologics, Communicable diseases, Drugs, HIV/AIDS, Human cells, tissues, and cellular and tissue-based products, Medical devices, Reporting and recordkeeping requirements.

42 CFR Part 121

Healthcare, Hospitals, Reporting and recordkeeping requirements.

■ 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, 21 CFR part 1271 and 42 CFR part 121 are amended as follows:

21 CFR Chapter I

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

■ 1. The authority citation for 21 CFR part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

■ 2. Section 1271.3 is amended by adding paragraph (d)(8) to read as follows:

§ 1271.3 How does FDA define important terms in this part?

* * * * *

(d) * * *

(8) Blood vessels recovered with an organ, as defined in 42 CFR 121.2, that are intended for use in organ transplantation and labeled ''For use in organ transplantation only.''

* * * * *

42 CFR Chapter I

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

■ 3. The authority citation for 42 CFR part 121 continues to read as follows:

Authority: Sections 215, 371–376 of the Public Health Service Act (42 U.S.C. 216, 273–274d); and sections 1102, 1106, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b–8 and 1395hh).

■ 4. Section 121.2 is amended by adding a sentence at the end of the definition of ''Organ'' to read as follows:

§ 121.2 Definitions

* * * * *

Organ * * * Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled ''For use in organ transplantation only.''

* * * * *

■ 5. Section 121.7 is amended by redesignating paragraph (e) as paragraph (f) and by adding paragraph (e) to read as follows:

§ 121.7 Identification of organ recipient.

* * * * *

(e) *Blood vessels considered part of an organ.* A blood vessel that is considered part of an organ under this part shall be subject to the allocation requirements and policies pertaining to the organ with which the blood vessel is procured until and unless the transplant center receiving the organ determines that the blood vessel is not needed for the transplantation of that organ.

* * * * *

Dated: December 8, 2006.

Elizabeth M. Duke,

Administrator, Health Resources and Services Administration.

Dated: February 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy, Food and Drug Administration.

[FR Doc. 07–1131 Filed 3–9–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–137F3]

RIN 1117–AA31

Exemption of Chemical Mixtures

AGENCY: Drug Enforcement Administration (DEA), U.S. Department of Justice.

ACTION: Final rule.

SUMMARY: On December 15, 2004, the Drug Enforcement Administration (DEA) published a Final Rule corrected January 4, 2005) that implemented new regulations concerning chemical mixtures that contain any of the 27 listed chemicals. The Final Rule added a new provision not previously raised by DEA in any proposed rulemaking. This newly introduced provision exempted domestic and import transactions in chemical mixtures that are regulated solely due to the presence of the List II solvent chemicals acetone, ethyl ether, 2-butanone, or toluene from the Controlled Substances Act (CSA) recordkeeping and reporting requirements. Because this exemption was not previously proposed in any rulemaking, DEA implemented this exemption on an interim basis and requested public comment on this exemption provision.

Based upon a review of all comments, DEA is finalizing this exemption. As such, domestic and import transactions in chemical mixtures containing the List II chemicals acetone, ethyl ether, 2-butanone, and toluene shall be exempt from CSA chemical recordkeeping and reporting requirements.

DATES: This Final Rule is effective March 12, 2007.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug & Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION:

I. Background

Historical Legal Status of Chemical Mixtures

The Chemical Diversion and Trafficking Act of 1988 (CDTA), (Pub. L. 100–690) created the definition of ''chemical mixture'' (21 U.S.C. 802(40)), and exempted chemical mixtures from regulatory control. The CDTA established 21 U.S.C. 802(39)(A)(vi), as amended by Title VII of Public Law 109–177, to exclude ''any transaction in a chemical mixture'' from the definition of a ''regulated transaction.'' The exemption of all chemical mixtures, however, provided traffickers with an unregulated source for obtaining listed chemicals for use in the illicit manufacture of controlled substances.

To remedy this situation, the Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200) (DCDCA), enacted in April 1994, subjected chemical mixtures containing listed chemicals to CSA regulatory requirements, unless specifically exempted by regulation. The DCDCA, therefore, subjected all regulated chemical mixtures to recordkeeping, reporting, and security requirements of the CSA. Additionally, the DCDCA added a registration requirement for handlers of regulated List I chemical mixtures.

The DCDCA, however, also amended 21 U.S.C. 802(39)(A)(vi), as amended by Title VII of Public Law 109–177, to provide the Attorney General with the authority to establish regulations exempting chemical mixtures from the definition of a ''regulated transaction'' ''based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered'' (21 U.S.C. 802(39)(A)(vi) as amended by Title VII of Pub. L. 109–177). This authority has been delegated to the Administrator of DEA by 28 CFR 0.100 and redelegated to the Deputy