prior to export to the United States, poultry and poultry products from Campeche, Quintana Roo, and Yucatan are not commingled with poultry and poultry products from END-affected regions. In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we submitted this information collection requirement for approval to the Office of Management and Budget (OMB). OMB has approved the information collection for a period of 6 months under control number 0579–0228. We plan, in the near future, to request continuation of that approval for 3 years.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

§ 94.6 [Amended]

■ 2. In § 94.6, paragraph (a)(2) is amended by adding the words ''Mexico (States of Campeche, Quintana Roo, and Yucatan),'' after the word ''Luxembourg,''.

■ 3. A new § 94.25 is added to read as follows:

§ 94.25 Restrictions on importation of live poultry, poultry meat, and other poultry products from specified regions.

The Mexican States of Campeche, Quintana Roo, and Yucatan, which are declared in § 94.6(a)(2) to be free of exotic Newcastle disease (END), supplement their meat supply by the importation of fresh (chilled or frozen) poultry meat from regions designated in § 94.6(a) as regions where END is considered to exist, have a common land border with regions where END is considered to exist, or import live poultry from regions where END is considered to exist under conditions less restrictive than would be acceptable for importation into the United States. Thus, even though the Department has declared such regions to be free of END, live poultry originating in such free regions may be commingled with live poultry originating in an END-affected region and the meat and other animal products produced in such free regions may be commingled with the fresh (chilled or frozen) meat of animals from an END-affected region, resulting in an undue risk of introducing END into the United States. Therefore, live poultry, poultry meat and other poultry products, and ship stores, airplane meals, and baggage containing such meat or animal products originating in the free regions listed in this section may not be imported into the United States unless the following requirements, in addition to all other applicable requirements of part 93 of this chapter and of chapter III of this title, are met:

(a) *Additional certification.* Live poultry, poultry meat, and other poultry products from any region designated in this section must be accompanied by an additional certification by a full-time salaried veterinary officer of the Government of Mexico. Upon arrival of the live poultry, poultry meat, or other poultry product in the United States, the certification must be presented to an authorized inspector at the port of arrival.

(b) *Live poultry.* The certification accompanying live poultry must identify the exporting region of the poultry as a region designated in § 94.6 as free of END at the time the poultry were in the region and must state that:

(1) The poultry have not been in contact with poultry or poultry products from any region where END is considered to exist;

(2) The poultry have not lived in a region where END is considered to exist; and

(3) The poultry have not transited through a region where END is considered to exist unless moved directly through the region in a sealed means of conveyance with the seal intact upon arrival at the point of destination.

(c) *Poultry meat or other poultry products.* The certification accompanying poultry meat or other poultry products must state that:

(1) The poultry meat or other poultry products are derived from poultry that meet all requirements of this section and that have been slaughtered in a region designated in § 94.6 as free of END at a federally inspected slaughter plant that is under the direct supervision of a full-time salaried veterinarian of the Government of Mexico and that is approved to export poultry meat and other poultry products to the United States in accordance with § 381.196 of this title;

(2) The poultry meat or other poultry products have not been in contact with poultry meat or other poultry products from any region where END is considered to exist;

(3) The poultry meat or other poultry products have not transited through a region where END is considered to exist unless moved directly through the region in a sealed means of conveyance with the seal intact upon arrival at the point of destination; and

(4) If processed, the poultry meat or other poultry products were processed in a region designated in § 94.6 as free of END in a federally inspected processing plant that is under the direct supervision of a full-time salaried veterinarian of the Government of Mexico.

(Approved by the Office of Management and Budget under control number 0579–0228)

Done in Washington, DC, this 21st day of January, 2004.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–1735 Filed 1–23–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. 97N–484R]

Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; opportunity for public comment.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final rule to except human dura mater and human heart valve allografts, currently subject to application or notification requirements under the Federal Food, Drug, and Cosmetic Act (the act), from the scope of the definition of ''human cells, tissues, or cellular or tissue-based products (HCT/P's)'' subject to the registration and listing requirements contained in 21 CFR part 1271. That definition became effective on January 21, 2004. FDA is taking this action to assure that these products, which are currently subject to the act and therefore regulated under the current good manufacturing practice regulations set out in the quality system regulations in 21 CFR part 820 are not released from the scope of those regulations before a more comprehensive regulatory framework applicable to HCT/P's, including donor suitability requirements, good tissue practice regulations, and appropriate enforcement provisions, is fully in place. When that comprehensive framework is in place, FDA intends that human dura mater and human heart valves will be subject to it. FDA intends to revoke this interim final rule at that time.

DATES: The interim final rule is effective January 23, 2004. The compliance date is March 29, 2004. Submit written or electronic comments on the interim final rule by April 26, 2004.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

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:

I. Background

In an earlier related rulemaking entitled ''Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing'' (66 FR 5447, January 19, 2001), the agency defined an HCT/P as ''articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.'' Examples of HCT/P's included, but were not limited to, ligaments, skin, bone, dura mater, heart valves, corneas, peripheral and cord blood hematopoietic stem cells, manipulated autologous chondrocytes, oocytes, and spermatozoa (66 FR at 5447 at 5467).

That rule further provided that HCT/P's meeting the criteria established in part 1271 (21 CFR part 1271) in § 1271.10 would be regulated solely under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264). The effect of these two provisions was that human dura mater and human heart valve allografts meeting the definition of HCT/P and the criteria in § 1271.10 for regulation solely under section 361 of the PHS Act would be removed from the scope of regulations established under the authority of the act. Instead they would be regulated solely under the comprehensive HCT/P regulations that the agency intended to issue under the authority of section 361 of the PHS Act. The agency intended to replace the current good manufacturing practice requirements applicable to human dura mater and human heart valve allografts, which provide protection against the risks of communicable disease and are set out in the Quality System Regulation under part 820 (21 CFR part 820), with donor suitability and good tissue practice regulations, which would be developed specifically to address the risks of communicable disease transmission.

Accordingly, at the time the registration and listing rule published, FDA had proposed two other rules to establish the remainder of that comprehensive regulatory framework:

- Suitability Determination for Donors of Human Cellular and Tissue-Based Products (64 FR 52696, September 30, 1999), and
- Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement (66 FR 1508, January 8, 2001).

When finalized, these three rules will establish a comprehensive regulatory framework for human cellular and tissue-based products, to be contained in part 1271. However, because all three regulations were not in place at the time the registration and listing rule published, the agency delayed, initially for 2 years, the effective date of the definition of HCT/P previously quoted. The agency made the registration and listing rule effective at first only for products currently regulated as human tissue intended for transplantation under 21 CFR part 1270. The agency explained that FDA did not intend to begin regulating human dura mater and human heart valve allografts that meet the criteria for regulation solely under section 361 of the PHS Act until the donor-suitability and good tissue practice (GTP) components of part 1271 become effective, or other appropriate steps have been taken. (66 FR at 5447 at 5453). Because finalizing the remaining two rules presented difficult issues and the rulemaking has taken more time than initially foreseen, FDA delayed the effective date for an additional year, until January 21, 2004 (68 FR 2689, January 21, 2003).

We (FDA) have now reached that date, and although work on the remaining two rules is nearing completion, the rules have not yet published. Rather than again delay the effective date of this provision, FDA believes that the provision should take effect, provided that the agency issues this interim final rule to assure that human dura mater and human heart valve allografts remain subject to appropriate provisions under the act, and including current good manufacturing practice requirements, until the comprehensive regulatory framework is in place. (FDA understands that many establishments may have reasonably expected FDA to delay the effective date of this provision again, because the donor suitability and GTP rules are not yet finalized. Once the comprehensive framework is in place, the agency intends to revoke this interim final rule, so that the comprehensive regulatory framework would then apply to human dura mater and human heart valve allografts, and these products would no longer be subject to regulation as medical devices under the act.

II. Legal Authority

FDA is issuing this regulation under the authority of section 361 of the PHS Act. Under that section, FDA 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. (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for delegation of section 361 of the PHS Act authority from the Surgeon General to the Secretary of the Department of Health and Human Services (the Secretary); See 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) Intrastate transactions affecting interstate communicable disease transmission may also be regulated under section 361 of the PHS Act. (See *Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977).) Until we put into place the new regulatory framework's remaining components, which are intended to

prevent the introduction, transmission, and spread of communicable diseases, it is necessary to preserve the applicability of regulations currently applicable to human dura mater and human heart valve allografts.

III. Issuance of an Interim Final Rule; Immediate Effective Date

Under the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(B) and FDA's administrative practices and procedures regulations at § 10.40(e)(1) (21 CFR 10.40(e)(1)), the Commissioner of Food and Drugs (the Commissioner) finds that use of prior notice and comment procedures for issuing this interim final rule is contrary to the public interest. In addition, the Commissioner finds good cause under 5 U.S.C. 553(d)(3) and § 10.40(c)(4)(ii) for making this interim final rule effective immediately upon filing at the Office of the Federal Register.

FDA concludes that this interim final rule is necessary to assure that human dura mater and human heart valve allografts, currently subject to good manufacturing practice regulatory requirements under the authority of the act, do not lose that protection during an interim period occurring between the date of their incorporation into the definition of HCT/P (January 21, 2004) and the effective date for the tissue donor suitability and GTP rules, to be finalized in the near future. Human dura mater and human heart valve allografts present significant risks of communicable disease transmission when the products are not handled properly. Absent this interim final rule, human dura mater and human heart valve allografts would fall within the definition of HCT/P's (§ 1271.3(d)(2)), and likely would also fall within the criteria for regulation solely under section 361 of the PHS Act (§ 1271.10). This would mean that human dura mater and human heart valve allografts would no longer be subject to the quality system regulation currently applicable to devices (part 820). If this occurred before the donor suitability and GTP rules became final, the public would lose the important public health protections afforded by the quality system regulation. In light of the significant public health risk that would be presented by these products if their manufacture were not subject to either a good tissue practice or current good manufacturing practice regulation, the Commissioner finds good cause to make these regulatory requirements final and effective immediately.

Although this agency is publishing this regulation as an interim final rule without an opportunity for prior notice and comment on a proposed rule, FDA is providing opportunity for comment on this interim final rule.

IV. Provisions of the Interim Final Rule

This interim final rule amends § 1271.3(d)(2) to delete the words ''dura mater and heart valves'' from the definition of ''Human cells, tissues, or cellular or tissue-based products (HCT/P's).'' It further adds new § 1271.3(d)(2)(viii), an exception to the definition of HCT/P's for human dura mater and human heart valve allografts. A minor change was necessary to § 1271.3(d)(2)(vi) and (d)(2)(vii) due to the addition of § 1271.3(d)(2)(viii).

V. Analysis of Impacts

FDA has examined the impacts of the interim final rule under Executive Order 12866 and the Regulatory Flexibility Act (Public Law 104–4), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1571), which are not applicable to interim final rules. 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 agency believes that this interim final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the interim final rule is not a significant regulatory action as defined by the Executive order. Therefore, FDA is not required under the Executive order to submit it to Office of Management and Budget (OMB) for review.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of proposed and final rules on small entities. Because this rule actually narrows the scope of the current regulation, this interim final rule does not impose in any new requirements. The agency certifies that the interim final rule will not have a significant economic impact on a substantial number of small entities. The Regulatory Flexibility Act requires no further analysis of this interim final rule.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits, before issuing any final rule that was the subject of a notice of proposed rulemaking and that may result in the expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation). The current inflation adjusted statutory threshold is about $110 million. FDA does not expect this interim final rule to result in any 1-year expenditure that would meet or exceed this amount. FDA is not required to prepare a written statement under the Unfunded Mandates Reform Act of 1995.

VI. The Paperwork Reduction Act of 1995

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

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(i) and 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.

VIII. Federalism

FDA has analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the interim final 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, the agency has concluded that the interim final 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.

IX. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this interim final rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 1271

Biologics, Drugs, Human cells and tissue-based products, Medical devices, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1271 is amended as follows:

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, 264, 271.

■ 2. Section 1271.3 is amended by revising the second sentence in the introductory text of paragraph (d)(2), by revising paragraphs (d)(2)(vi) and (d)(2)(vii), and by adding paragraph (d)(2)(viii) to read as follows:

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

* * * * *

(d) * * *

(2) * * * Examples of HCT/P's include, but are not limited to, bone, ligament, skin, cornea, hematopoietic stem cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue.* * *

* * * * * *

(vi) Cells, tissues, and organs derived from animals other than humans;

(vii) In vitro diagnostic products as defined in § 809.3(a) of this chapter; and

(viii) Human dura mater and human heart valve allografts.

* * * * *

Dated: January 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–1733 Filed 1–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9112]

RIN 1545–BC90

Low-Income Housing Credit Allocation Certification; Electronic Filing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains regulations that facilitate the electronic filing of Form 8609, ''Low-Income Housing Credit Allocation Certification.'' The regulations affect taxpayers who file Form 8609.

DATES: *Effective Date:* These regulations are effective January 27, 2004.

Date of Applicability: For date of applicability, *see* § 1.42–1(j).

FOR FURTHER INFORMATION CONTACT: Paul F. Handleman, (202) 622–3040 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

In 1998, Congress enacted the Internal Revenue Service Restructuring and Reform Act of 1998 (RRA 1998), Public Law 105–206 (112 Stat. 685) (1998). Section 2001(a) of RRA 1998 states that the policy of Congress is that paperless filing should be the preferred and most convenient means of filing Federal tax returns. Section 2001(a) of RRA 1998 also sets a long-range goal for the IRS to have at least 80 percent of all Federal tax returns filed electronically by 2007. Section 2001(b) of RRA 1998 requires the IRS to establish a 10-year strategic plan to eliminate barriers to electronic filing.

The IRS has identified § 1.42–1T(e)(1) and (h)(2) as regulatory provisions that impede electronic filing of Form 8609, ''Low-Income Housing Credit Allocation Certification,'' by requiring a taxpayer to include a third-party signature from an authorized State or local housing credit agency (Agency) official when filing the form. This Treasury decision eliminates that requirement.

Explanation of Provisions

Section 42 provides for a low-income housing credit that may be claimed as part of the general business credit under section 38. In general, the credit is allowable only if the owner of a qualified low-income building receives a housing credit allocation from an Agency of the jurisdiction where the building is located.

Section 1.42–1T(d)(8)(ii) provides that housing credit allocations are deemed made when Part I of Form 8609 is completed and signed by an authorized Agency official and mailed to the owner of the qualified low-income building. Under § 1.42–1T(e)(1), an owner is required to complete the Form 8609 on which the Agency made the applicable housing credit allocation and submit a copy of it with the owner's Federal income tax return for each year in the compliance period. Under § 1.42–1T(h)(2), the owner is required to file a completed Form 8609 (or copy thereof) with the owner's Federal income tax return for each of the 15 taxable years in the compliance period. Section 1.42–1T(h)(2) also provides other rules for completing Form 8609.

This Treasury decision facilitates the electronic filing of Federal tax returns by eliminating the requirements in § 1.42–1T(e)(1) and (h)(2) that an owner file a copy of the completed Form 8609 that is signed by the authorized Agency official with the owner's Federal income tax return for each of the 15 taxable years in the compliance period. Notwithstanding that the owner need not file a copy of the Form 8609 signed by the Agency official, the building owner must continue to retain that form for 3 years after the due date, including extensions, of the building owner's tax return for the tax year that includes the end of the 15-year compliance period. The other rules in § 1.42–1T(h)(2) for completing Form 8609 are also deleted. The requirements for completing and filing Form 8609 are addressed in the instructions to the form.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) and (d) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Paul F. Handleman, Office of the Associate Chief Counsel (Passthroughs and Special Industries), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is amended as follows: