Regulatory Flexibility Act and Executive Order 12866

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. This amendment does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

Signing Authority

This document is limited to a technical correction of CBP regulations. Accordingly, it is being signed under the authority of 19 CFR 0.1(b).

List of Subjects in 19 CFR Part 122

Air carriers, Aircraft, Airports, Customs duties and inspection, Freight.

Amendments to Regulations

■ Part 122, Code of Federal Regulations (19 CFR part 122) is amended as set forth below:

PART 122—AIR COMMERCE REGULATIONS

■ 1. The authority citation for part 122 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1431, 1433, 1436, 1448, 1459, 1590, 1594, 1623, 1624, 1644, 1644a, 2071 note.

§ 122.15 [Amended]

■ 2. The listing of user fee airports in § 122.15(b) is amended by removing from the ''Location'' column, ''Santa Maria, California,'' and by removing on the same line, from the ''Name'' column, ''Santa Maria Public Airport.''

Dated: October 15, 2009.

Jayson P. Ahern,

Acting Commissioner, U.S. Customs and Border Protection.

[FR Doc. E9–25321 Filed 10–20–09; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

19 CFR Part 122

[CBP Dec. 09–41]

Technical Amendments to List of User Fee Airports: Removal of User Fee Status for Roswell Industrial Air Center, Roswell, NM and March Inland Port Airport, Riverside, CA and Name Change for Capital City Airport, Lansing, MI

AGENCY: Customs and Border Protection, DHS.

ACTION: Final rule; technical amendments.

SUMMARY: This document amends the Customs and Border Protection (CBP) Regulations by revising the list of user fee airports to reflect the removal of the user fee designations for the Roswell Industrial Air Center in Roswell, New Mexico and the March Inland Port Airport in Riverside, California, as well as indicating that the Capital City Airport in Lansing, Michigan has changed its name to the Capital Region International Airport. User fee airports are those airports which, while not qualifying for designation as international or landing rights airports, have been approved by the Commissioner of CBP to receive, for a fee, the services of CBP officers for the processing of aircraft entering the United States, and the passengers and cargo of those aircraft.

DATES: *Effective Date:* October 21, 2009.

FOR FURTHER INFORMATION CONTACT: Wendy M. Cooper, Office of Field Operations, 202–344–2057.

SUPPLEMENTARY INFORMATION:

Background

Title 19, Part 122, Code of Federal Regulations (CFR), sets forth regulations relating to the entry and clearance of aircraft in international commerce and the transportation of persons and cargo by aircraft in international commerce.

Generally, a civil aircraft arriving from a place outside of the United States is required to land at an airport designated as an international airport. Alternatively, the pilot of a civil aircraft may request permission to land at a specific airport, and, if landing rights are granted, the civil aircraft may land at that landing rights airport.

Section 236 of Public Law 98–573 (the Trade and Tariff Act of 1984), codified at 19 U.S.C. 58b, created an option for civil aircraft desiring to land at an airport other than an international airport or a landing rights airport. A civil aircraft arriving from a place outside of the United States may ask for permission to land at an airport designated by the Secretary of Homeland Security [1] as a user fee airport.

Pursuant to 19 U.S.C. 58b, an airport may be designated as a user fee airport if the Commissioner of CBP as delegated by the Secretary of Homeland Security determines that the volume of business at the airport is insufficient to justify customs services at the airport and the governor of the state in which the airport is located approves the designation. Generally, the type of airport that would seek designation as a user fee airport would be one at which a company, such as an air courier service, has a specialized interest in regularly landing.

As the volume of business anticipated at this type of airport is insufficient to justify its designation as an international or landing rights airport, the availability of customs services is not paid for out of appropriations from the general treasury of the United States. Instead, customs services are provided on a fully reimbursable basis to be paid for by the user fee airport on behalf of the recipients of the services.

Pursuant to 19 U.S.C. 58b, the fees which are to be charged at user fee airports shall be paid by each person using the customs services at the airport and shall be in the amount equal to the expenses incurred by the Commissioner of CBP in providing customs services which are rendered to such person at such airport, including the salary and expenses of those employed by the Commissioner of CBP to provide the customs services. To implement this provision, the airport seeking the designation as a user fee airport or that airport's authority generally agrees to pay a flat fee for which the users of the airport are to reimburse the airport/airport authority. The airport/airport authority agrees to set and periodically review the charges to ensure that they are in accord with the airport's expenses.

The Commissioner of CBP designates airports as user fee airports pursuant to 19 U.S.C. 58b. *See* 19 CFR 122.15. If the Commissioner decides that the conditions for designation as a user fee airport are satisfied, a Memorandum of Agreement (MOA) is executed between the Commissioner of CBP and the local responsible official signing on behalf of the state, city or municipality in which the airport is located. In this manner, user fee airports are designated on a case-by-case basis. Periodically, CBP updates the list of user fee airports at 19 CFR 122.15(b) to reflect changes in the status of user fee airports.

Recent Changes Requiring Updates to the List of User Fee Airports

Section 19 CFR 122.15(c)(1) provides that the designation as a user fee airport

[1] Sections 403(1) and 411 of the Homeland Security Act of 2002 (''the Act,'' Pub. L. 107–296) transferred the United States Customs Service and its functions from the Department of the Treasury to the Department of Homeland Security; pursuant to section 1502 of the Act, the President renamed the ''Customs Service'' as the ''Bureau of Customs and Border Protection.'' Effective on March 31, 2007, DHS changed the name of ''Bureau of Customs and Border Protection'' to ''U.S. Customs and Border Protection (CBP)'' (*See* 72 FR 20131, April 23, 2007).

shall be withdrawn if either CBP or the airport authority gives 120 days written notice of termination to the other party. On January 15, 2009, CBP gave written notice to the Roswell Industrial Air Center in Roswell, New Mexico terminating their status as a user fee facility, in accordance with 19 CFR 122.15(c)(1). On November 6, 2008, the March Inland Port Airport Authority gave written notice terminating their MOA with CBP, in accordance with 19 CFR 122.15(c)(1).

On January 26, 2009, Capital City Airport notified CBP that it had officially changed its name to the Capital Region International Airport.

This document updates the list of user fee airports by deleting the Roswell Industrial Air Center in Roswell, New Mexico and the March Inland Port Airport in Riverside, California, and changing the name of the Capital City Airport in Lansing, Michigan to the Capital Region International Airport.

Inapplicability of Public Notice and Delayed Effective Date Requirements

Because this amendment merely updates the list of user fee airports to reflect a name change and to remove airports already approved for withdrawal by the Commissioner of CBP in accordance with 19 CFR 122.15(c)(1) and neither imposes additional burdens on, nor takes away any existing rights or privileges from, the public, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure are unnecessary, and for the same reasons, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

The Regulatory Flexibility Act and Executive Order 12866

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. This amendment does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

Signing Authority

This document is limited to technical corrections of CBP regulations. Accordingly, it is being signed under the authority of 19 CFR 0.1(b).

List of Subjects in 19 CFR Part 122

Air carriers, Aircraft, Airports, Customs duties and inspection, Freight.

Amendments to Regulations

■ Part 122, Code of Federal Regulations (19 CFR part 122) is amended as set forth below:

PART 122—AIR COMMERCE REGULATIONS

■ 1. The authority citation for part 122 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1431, 1433, 1436, 1448, 1459, 1590, 1594, 1623, 1624, 1644, 1644a, 2071 note.

§ 122.15 [Amended]

■ 2. The listing of user fee airports in § 122.15(b) is amended as follows: by removing, in the ''Location'' column, ''Roswell, New Mexico'' and by removing on the same line, in the ''Name'' column, ''Roswell Air Industrial Center.''; by removing, in the ''Location'' column, ''Riverside, California'' and by removing on the same line, in the ''Name'' column, ''March Inland Port Airport.''; and, by removing, in the ''Name'' column, ''Capital City Airport'' and adding in its place ''Capital Region International Airport.''

Dated: October 15, 2009.

Jayson P. Ahern,

Acting Commissioner, Customs and Border Protection.

[FR Doc. E9–25318 Filed 10–20–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2009–N–0472]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Cardiac Allograft Gene Expression Profiling Test Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the classification of cardiac allograft gene expression profiling test systems into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems.'' FDA classified the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

DATES: This final rule is effective November 20, 2009. The classification was effective August 26, 2008.

FOR FURTHER INFORMATION CONTACT: Kellie B. Kelm, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5625, Silver Spring, MD 20993, 301–796–6145.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on August 8, 2008, classifying the XDx AlloMap Test in class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On August 15, 2008, XDx, Inc., submitted a petition requesting