Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA has analyzed this rescission under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it is not a ''significant energy action'' under the executive order because while a ''significant regulatory action'' under Executive Order 12866, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Availability of Rulemaking Documents

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You may access all documents the FAA considered in developing this rescission from the internet through the Federal eRulemaking Portal referenced in paragraph (1).

List of Subjects in 14 CFR Part 93

Air traffic control, Airports, Navigation (air), Reporting and recordkeeping requirements.

The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends Chapter I of Title 14, Code of Federal Regulations, as follows:

PART 93—SPECIAL AIR TRAFFIC RULES

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40109, 40113, 44502, 44514, 44701, 44719, 46301.

Subpart C—[Removed and Reserved]

■ 2. Remove and reserve Subpart C of Part 93.

Issued in Washington, DC, on October 1, 2009.

J. Randolph Babbitt,

Administrator.

[FR Doc. E9–24232 Filed 10–8–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

[Docket No. FAA–2008–0517; Notice No. 93–93]

RIN 2120–AJ48

Congestion Management Rule for John F. Kennedy International Airport and Newark Liberty International Airport

AGENCY: Federal Aviation Administration (FAA).

ACTION: Final rule; rescission.

SUMMARY: The FAA is rescinding the final rule *Congestion Management Rule for John F. Kennedy International Airport and Newark Liberty International Airport.* The final rule established procedures to address congestion in the New York City area by assigning slots for scheduled services at John F. Kennedy (JFK) and Newark Liberty (Newark) International Airports, assigning to existing operators the majority of slots at the airports, and creating a market by annually auctioning off a limited number of slots in each of the first five years of the rule. The final rule also contained provisions for minimum usage, requiring reservations for unscheduled operations, and withdrawal for operational need. The rule was scheduled to sunset in ten years.

DATES: *Effective Date:* October 9, 2009.

FOR FURTHER INFORMATION CONTACT: For questions concerning this rulemaking, contact: Molly W. Smith, Office of Aviation Policy and Plans, APO–200, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3275; e-mail *molly.w.smith@faa.gov*. For legal questions concerning this rulemaking, contact: Rebecca MacPherson, FAA Office of the Chief Counsel, 800 Independence Ave., SW., Washington, DC 20591; telephone (202) 267–3073; e-mail *rebecca.macpherson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA has broad authority under 49 U.S.C. 40103 to regulate the use of the navigable airspace of the United States. This section authorizes the FAA to develop plans and policy for the use of navigable airspace and to assign the use that the FAA deems necessary for its safe and efficient utilization. It further directs the FAA to prescribe air traffic rules and regulations governing the efficient utilization of thenavigable airspace.

I. Background

The final rule *Congestion Management Rule for John F. Kennedy International Airport and Newark Liberty International Airport* was published in the **Federal Register** on October 10, 2008 (73 FR 60544) (2008 final rule). The 2008 final rule established procedures to address congestion in the New York City area by assigning slots at John F. Kennedy (JFK) and Newark Liberty (Newark) International Airports, assigning to existing operators the majority of slots at the airports, and creating a market by annually auctioning off a limited number of slots in each of the first five years of the rule. The final rule also contained provisions for minimum slot usage, withdrawal of slots for operational need, and requiring reservations for unscheduled operations. The rule was scheduled to sunset in ten years and added to the Code of Federal Regulations December 9, 2008. The rulemaking was highly controversial. The final rule was challenged by several parties before it could take effect. On December 8, 2008, the United States Court of Appeals for the District of Columbia Circuit stayed the rule. On January 22, 2009, the ATA requested the Secretary of Transportation, Ray LaHood, withdraw the final rule in light of the court's stay. While the regulations were incorporated into the Code of Federal Regulations, due to the courts ruling, they had no force and effect.

On March 11, 2009, the President signed Public Law 111–8, Omnibus Appropriations Act, 2009. That legislation provides several departments within the executive branch, including the Department of Transportation, with the funds to operate until the end of this fiscal year. That legislation also contains a provision in Division I, section 115 that prohibits the Secretary of Transportation from promulgating regulations or taking any action regarding the scheduling of airline operations that involve auctioning rights or permission to conduct airline operations at such an airport or withdrawing a right or permission to conduct operations at such an airport (except when the withdrawal is for operational reasons or pursuant to the

terms or conditions of such operating right or permission). The prohibition is limited to this fiscal year.

At present, both airports remain limited by order at 81 scheduled operations per hour until October 2009. *Order Limiting Scheduled Operations at John F. Kennedy International Airport* (73 FR 3519 (Jan. 18, 2008), as amended 73 FR 8737 (Feb. 14, 2008)); *Order Limiting Scheduled Operations at Newark Liberty International Airport* (73 FR 29550 (May 21, 2008)).

On May 14, 2009 the FAA published a notice proposing to rescind the 2008 final rule citing the impact of the Omnibus Appropriations Act on the rule and the state of the economy in general. The comment period closed June 15, 2009. The FAA received six sets of comments, all of which supported rescission of the rule.

For the reasons stated in the NPRM, the FAA has decided to rescind the 2008 final rule effective immediately. The FAA has determined that good cause exists for implementing this rule immediately. As discussed above, the rule has been stayed by court action and has not been implemented. Accordingly, no further action is required by the regulated parties and delaying the effective date serves no useful purpose. The agency will consider its options with regard to managing congestion at the airport in ways that provide a means for carriers either to commence or expand operations at the airport in future rulemaking.

In order to prevent over-scheduling at JFK and Newark while the agency considers alternative congestion management options the FAA has published orders to show cause proposing to extend the existing orders until October 2010. 74 FR 27059 (June 5, 2009); 74 FR 27060 (June 5, 2009).

II. Regulatory Notices and Analyses

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. 4 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, to be the basis of U.S. standards. Fourth, the Unfunded Mandate Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation). The FAA currently uses an inflation-adjusted value of $136.1 million in lieu of $100 million.

The FAA conducted all of these analyses when it originally issued the 2008 final rule. The agency has determined the rescission does not require any further economic analysis. Practically speaking, due to the rescission, the status quo remains in effect, and neither costs nor benefits anticipated by the final rule will accrue. Likewise, the paperwork burden anticipated under the rule will not be imposed on any parties. The FAA has already determined that the rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act. Rescission of the 2008 final rule likewise imposes no such burden. As the rescission of the 2008 final rule does not impose any standard on any party, the FAA has assessed the potential effect of this rescission and determined that it will impose no costs on international entities and thus have a no trade impact. Nor will the rescission impose a Federal mandate that may result in an expenditure of $100 million or more (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, and the requirements of Title II of the Unfunded Mandate Reform Act of 1995 do not apply.

The rescission of the 2008 final rule is a ''significant regulatory action'' under Executive Order 12866 and is ''significant'' as defined in DOT's Regulatory Policies and Procedures. Accordingly, it has been reviewed by DOT and OMB.

Executive Order 13132, Federalism

The FAA has analyzed this rescission under the principles and criteria of Executive Order 13132, Federalism. We have determined that this action will not have a substantial direct effect 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, and, therefore, does not have federalism implications.

Environmental Analysis

FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures'' identifies FAA actions that are normally categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act (NEPA) in the absence of extraordinary circumstances The FAA previously determined that the final rule qualified for the categorical exclusions identified in paragraph 312d ''Issuance of regulatory documents (*e.g.,* Notices of Proposed Rulemaking and issuance of Final Rules) covering administration or procedural requirements (does not include Air Traffic procedures; specific Air traffic procedures that are categorically excluded are identified under paragraph 311 of this Order)'' and paragraph 312f, ''Regulations, standards, and exemptions (excluding those which if implemented may cause a significant impact on the human environment.'' It has further been determined that no extraordinary circumstances exist that may cause a significant impact and therefore no further environmental review is required. The FAA documented this categorical exclusion determination. A copy of the determination and underlying documents has been included in the Docket for the rule. The FAA has determined that the rescission of the 2008 final rule also qualifies for a categorical exclusion since it will have no impact on the environment.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

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Subpart N—[Removed and Reserved]

■ 2. Remove and reserve Subpart N of Part 93.

Issued in Washington, DC, on October 1, 2009.

J. Randolph Babbitt,

Administrator.

[FR Doc. E9–24235 Filed 10–8–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2009–N–0119]

Medical Devices; Immunology and Microbiology Devices; Classification of Respiratory Viral Panel Multiplex Nucleic Acid Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the classification of the respiratory viral panel multiplex nucleic acid assay into class II (special controls). The special controls that will apply to the device are three guidance documents entitled: ''Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay,'' as applicable, ''Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays,'' and as applicable,''Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays.'' The agency 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 documents that will serve as the special controls for this device.

DATES: This final rule is effective November 9, 2009. The classification was effective January 3, 2008.

FOR FURTHER INFORMATION CONTACT: Zivana Tezak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5550, Silver Spring, MD 20993, 301–796–6204.

SUPPLEMENTARY INFORMATION:

I. What Is the Background of This Rulemaking?

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 and until 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 such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on November 30, 2007, classifying the Luminex Molecular Diagnostics, Inc., xTAG™ RVP (Respiratory Viral Panel) as 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 December 1, 2007, Luminex Molecular Diagnostics, Inc., submitted a petition requesting classification of the xTAG™ RVP under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Luminex Molecular Diagnostics, Inc., xTAG™ RVP can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name ''respiratory viral panel multiplex nucleic acid assay.'' It is identified as a qualitative in vitro diagnostic device that is intended to simultaneously detect and identify multiple viral nucleic acids extracted from human respiratory specimens or viral culture. The detection and identification of a specific viral nucleic acid from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection when used in conjunction with other clinical and laboratory findings.