DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No.: FAA–2014–0225; Amdt. No. 91–331B]

RIN 2120–AK78

Extension of the Prohibition Against Certain Flights in the Simferopol (UKFV) and Dnipropetrovsk (UKDV) Flight Information Regions (FIRs)

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This action extends the prohibition against certain flight operations in the Simferopol (UKFV) and Dnipropetrovsk (UKDV) flight information regions (FIRs) by all United States (U.S.) air carriers; U.S. commercial operators; persons exercising the privileges of a U.S. airman certificate, except when such persons are operating a U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when such operators are foreign air carriers. This action also revises the FAA approval process for proposed operations authorized by other U.S. Government departments, agencies, and instrumentalities to clarify the FAA's expectations regarding requests for approval and revises the approval conditions and information about requests for exemptions to reflect the termination of statutory authorization for the FAA's premium war risk insurance program. This action also makes minor non-substantive corrections to the wording of the rule. The FAA finds this action to be necessary to address a continuing hazard to persons and aircraft engaged in such flight operations.

DATES: This final rule is effective on October 22, 2015.

FOR FURTHER INFORMATION CONTACT: Michael Filippell, Air Transportation Division, AFS–220, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8166; email: *michael.e.filippell@faa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

This action continues the prohibition on flight operations in the UKFV and UKDV FIRs by all U.S. air carriers; U.S. commercial operators; persons exercising the privileges of a U.S. airman certificate, except when such persons are operating a U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when such operators are foreign air carriers. This action also revises the FAA approval process for proposed operations authorized by other U.S. Government departments, agencies, and instrumentalities to clarify the FAA's expectations regarding requests for approval and revises the approval conditions and information about requests for exemptions to reflect the termination of statutory authorization for the FAA's premium war risk insurance program. This action also makes minor non-substantive corrections to the wording of the rule. The FAA finds this action necessary to address a continuing hazard to persons and aircraft engaged in such flight operations.

II. Good Cause for Immediate Adoption

Section 553(b)(3)(B) of title 5, U.S. Code, authorizes agencies to dispense with notice and comment procedures for rules when the agency for ''good cause'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' In this instance, the FAA finds that notice and public comment to this immediately adopted final rule, as well as any delay in the effective date of this rule, are contrary to the public interest due to the immediate need to address the hazard to U.S. civil aviation that continues to exist in the UKFV and UKDV FIRs, as described in the Background section of this rule.

III. Authority for This Rulemaking

The FAA is responsible for the safety of flight in the U.S. and for the safety of U.S. civil operators, U.S.-registered civil aircraft, and U.S.-certificated airmen throughout the world. The FAA's authority to issue rules on aviation safety is found in title 49, U.S. Code. Subtitle I, section 106(f), describes the authority of the FAA Administrator. Section 40101(d)(1) provides that the Administrator shall consider in the public interest, among other matters, assigning, maintaining, and enhancing safety and security as the highest priorities in air commerce. Section 40105(b)(1)(A) requires the Administrator to exercise his authority consistently with the obligations of the U.S. Government under international agreements.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, subpart III, section 44701, General requirements. Under that section, the FAA is charged broadly with promoting safe flight of civil aircraft in air commerce by prescribing, among other things, regulations and minimum standards for practices, methods, and procedures that the Administrator finds necessary for safety in air commerce and national security. This regulation is within the scope of that authority because it continues to prohibit the persons subject to paragraph (a) of SFAR No. 113, § 91.1607, from conducting flight operations in the UKFV and UKDV FIRs due to the hazard to the safety of such persons' flight operations, as described in the Background section of this rule.

IV. Background

On April 25, 2014, the FAA published SFAR No. 113, § 91.1607, which prohibited flight operations in a portion of the UKFV FIR by all U.S. air carriers; U.S. commercial operators; persons exercising the privileges of a U.S. airman certificate, except when such persons were operating a U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when such operators were foreign air carriers (79 FR 22862). At that time, the FAA viewed the possibility of civil aircraft receiving confusing and conflicting air traffic control instructions from both Ukrainian and Russian air traffic service providers when operating in the portion of the Simferopol (UKFV) FIR covered by SFAR No. 113, § 91.1607, as an unsafe condition that presented a potential hazard to U.S. civil flight operations in the disputed airspace. Because political and military tensions between Ukraine and the Russian Federation remained high, the FAA was also concerned that compliance with air traffic control instructions issued by the authorities of one country could result in a civil aircraft being misidentified as a threat and intercepted or otherwise engaged by air defense forces of the other country. The FAA continues to have these concerns.

On July 18, 2014 (UTC), the FAA expanded its flight prohibition through the issuance of Notice to Airmen (NOTAM) FDC 4/2182, due to ongoing safety concerns regarding U.S. civil flight operations in the entire UKFV and UKDV FIRs. The FAA determined that the ongoing conflict in the region posed a significant threat to U.S. civil aviation operations in these FIRs. In addition to a series of attacks on fixed-wing and rotary-wing Ukrainian military aircraft flying at lower altitudes, a Ukrainian An-26 flying at 21,000 feet southeast of Luhansk was shot down on July 14, 2014, and a Malaysia Airlines Boeing 777 was shot down on July 17, 2014,

while flying over Ukraine at 33,000 feet just west of the Russian border. Two hundred ninety eight passengers and crew perished. The use of weapons capable of targeting and shooting down aircraft flying on civil air routes at cruising altitudes posed a significantly dangerous threat to civil aircraft flying in the UKFV and UKDV FIRs. The FAA published a final rule incorporating the expanded flight prohibition into SFAR No. 113, § 91.1607, on December 29, 2014 (79 FR 77857).

The FAA has continued to evaluate the situation in the UKFV and UKDV FIRs and has determined there is a continuing significant flight safety hazard to U.S. civil aviation from the ongoing risk of skirmishes in the area. There is also a potential for larger-scale fighting in eastern Ukraine involving pro-Russian separatists, which could result in civil aircraft being misidentified as a threat and then intercepted or otherwise engaged, as demonstrated by the shoot down of Malaysia Airlines Flight 17 on July 17, 2014. Pro-Russian separatists have access to a variety of anti-aircraft weapons, to include man-portable air defense systems (MANPADS) and possibly more advanced surface-to-air-missiles (SAMs) that have the capability to engage aircraft at higher altitudes. Separatists have demonstrated their ability to use these anti-aircraft weapons by successfully shooting down a number of aircraft during the course of the fighting in eastern Ukraine in 2014. There is also continuing concern over the hazard to U.S. civil aviation from possible conflicting air traffic control instructions from Ukrainian and Russian air traffic service providers due to a dispute over responsibility for providing air navigation services in portions of the Simferopol (UKFV) FIR. In addition, there have been reported incidents of purposeful interference, including GPS jamming, in the UKFV and UKDV FIRs.

Due to the previously described continuing hazards to U.S. civil aviation operations, the FAA is extending the expiration date of SFAR No. 113, § 91.1607, to continue the prohibition on flight operations in the UKFV and UKDV FIRs by all U.S. air carriers; U.S. commercial operators; persons exercising the privileges of a U.S. airman certificate, except when such persons are operating a U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when such operators are foreign air carriers. This rule extends the expiration date of SFAR No. 113, § 91.1607, from October 27, 2015, to October 27, 2016.

The FAA will continue to actively evaluate the area to determine to what extent U.S. civil aviation may be able to safely operate therein. Adjustments to this SFAR may be appropriate if the risk to aviation safety and security changes. The FAA may amend or rescind this SFAR as necessary prior to its expiration date.

Additionally, the FAA is revising its approval process for proposed operations authorized by other U.S. Government departments, agencies, and instrumentalities to clarify the FAA's expectations regarding requests for approval. The FAA is also revising the approval conditions that will apply to operations authorized by other U.S. Government departments, agencies, and instrumentalities and approved by the FAA, and the information about requests for exemption, to reflect the termination of statutory authorization for the FAA premium war risk insurance program. Section 102 of Division L of the Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235, December 16, 2014, *inter alia,* amended 49 U.S.C. 44302(f) and 44310(a) to specify the termination dates in those sections as December 11, 2014. The effect was to terminate coverage under FAA's premium war risk insurance program as of December 11, 2014. This action also makes minor non-substantive corrections to the wording of the rule.

Because the circumstances described herein warrant immediate action by the FAA, I find that notice and public comment under 5 U.S.C. 553(b)(3)(B) are impracticable and contrary to the public interest. Further, I find that good cause exists under 5 U.S.C. 553(d) for making this rule effective immediately upon issuance. I also find that this action is fully consistent with the obligations under 49 U.S.C. 40105 to ensure that I exercise my duties consistently with the obligations of the United States under international agreements.

V. Revised Approval Process Based on a Request From a Department, Agency, or Instrumentality of the United States Government

If a department, agency, or instrumentality of the U.S. Government determines that it has a critical need to engage any person covered under SFAR No. 113, § 91.1607, including a U.S. air carrier or a U.S. commercial operator, to conduct a charter to transport civilian or military passengers or cargo or other operations in either or both of the UKFV and UKDV FIRs, that department, agency, or instrumentality may request that the FAA approve persons covered under SFAR No. 113, § 91.1607, to conduct such operations. An approval request must be made directly by the requesting department, agency, or instrumentality of the U.S. Government to the FAA's Associate Administrator for Aviation Safety (AVS–1) in a letter signed by an appropriate senior official of the requesting department, agency, or instrumentality. Requests for approval submitted to the FAA by anyone other than the requesting department, agency, or instrumentality will not be accepted and will not be processed. In addition, the senior official signing the letter requesting FAA approval on behalf of the requesting department, agency, or instrumentality must be sufficiently highly placed within his or her organization to demonstrate that the senior leadership of the requesting department, agency, or instrumentality supports the request for approval and is committed to taking all necessary steps to minimize operational risks to the proposed flights. The senior official must also be in a position to: (1) Attest to the accuracy of all representations made to the FAA in the request for approval and (2) ensure that any support from the requesting U.S. government department, agency, or instrumentality described in the request for approval is in fact brought to bear and is maintained over time. Unless exigent circumstances exist, requests for approval must be submitted to the FAA not less than 30 calendar days before the date on which the requesting department, agency, or instrumentality wishes the proposed operations, if approved by the FAA, to commence.

The letter must be sent by the requesting department, agency, or instrumentality to the Associate Administrator for Aviation Safety (AVS–1), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591. Electronic submissions are acceptable, and the requesting entity may request that the FAA notify it electronically as to whether the approval request is granted. If a requestor wishes to make an electronic submission to the FAA, the requestor should contact the Air Transportation Division, Flight Standards Service, at (202) 267–8166 to obtain the appropriate email address. A single letter may request approval from the FAA for multiple persons covered under SFAR No. 113, § 91.1607, and/or for multiple flight operations. To the extent known, the letter must identify the person(s) expected to be covered under the SFAR on whose behalf the U.S. Government department, agency, or instrumentality is seeking FAA approval, and it must describe—

• The proposed operation(s), including the nature of the mission being supported;
• The service to be provided by the person(s) covered by the SFAR;
• To the extent known, the specific locations in either or both of the Simferopol (UKFV) and Dnipropetrovsk (UKDV) FIRs where the proposed operation(s) will be conducted, including, but not limited to, the flight path and altitude of the aircraft while it is operating in either or both of the Simferopol (UKFV) and Dnipropetrovsk (UKDV) FIRs and the airports, airfields and/or landing zones at which the aircraft will take-off and land; and
• The method by which the department, agency, or instrumentality will provide, or how the operator will otherwise obtain, current threat information and an explanation of how the operator will integrate this information into all phases of its proposed operations (*e.g.,* pre-mission planning and briefing, in-flight, and post-flight).

The request for approval must also include a list of operators with whom the U.S. Government department, agency, or instrumentality requesting FAA approval has a current contract(s), grant(s), or cooperative agreement(s) (or with whom its prime contractor has a subcontract(s)) for specific flight operations in either or both of the UKFV and UKDV FIRs. Additional operators may be identified to the FAA at any time after the FAA approval is issued. However, all additional operators must be identified to, and obtain an Operations Specification (OpSpec) or Letter of Authorization (LOA), as appropriate, from, the FAA, for operations in either or both of the UKFV and UKDV FIRs before such operators commence such operations. The revised approval conditions discussed below will apply to any such additional operators. Updated lists should be sent to the email address to be obtained from the Air Transportation Division by calling (202) 267–8166.

If an approval request includes classified information, requestors may contact Aviation Safety Inspector Michael Filippell for instructions on submitting it to the FAA. His contact information is listed in the ''For Further Information Contact'' section of this final rule.

FAA approval of an operation under SFAR No. 113, § 91.1607, does not relieve persons subject to this SFAR of their responsibility to comply with all applicable FAA rules and regulations. Operators of civil aircraft must also comply with the conditions of their certificate, OpSpecs, and LOAs, as applicable. Operators must further comply with all rules and regulations of other U.S. Government departments and agencies that may apply to the proposed operation, including, but not limited to, the Transportation Security Regulations issued by the Transportation Security Administration, Department of Homeland Security.

Revised Approval Conditions

If the FAA approves the request, the FAA's Aviation Safety Organization (AVS) will send an approval letter to the requesting department, agency, or instrumentality informing it that the FAA's approval is subject to all of the following conditions:

(1) The approval will stipulate those procedures and conditions that limit, to the greatest degree possible, the risk to the operator, while still allowing the operator to achieve its operational objectives.

(2) Before any approval takes effect, the operator must submit to the FAA:

(a) A written release of the U.S. Government from all damages, claims, and liabilities, including without limitation legal fees and expenses; and

(b) The operator's agreement to indemnify the U.S. Government with respect to any and all third-party damages, claims, and liabilities, including without limitation legal fees and expenses, relating to any event arising from or related to the approved operations in either or both of the UKFV and UKDV FIRs.

(3) Other conditions that the FAA may specify, including those that may be imposed in OpSpecs or LOAs, as applicable.

The release and agreement to indemnify do not preclude an operator from raising a claim under an applicable non-premium war risk insurance policy issued by the FAA under chapter 443 of title 49, United States Code.

If the proposed operation or operations are approved, the FAA will issue an OpSpec or an LOA, as applicable, to the operator authorizing the operation or operations, and will notify the department, agency, or instrumentality that requested the FAA's approval of any additional conditions beyond those contained in the approval letter. The requesting department, agency, or instrumentality must have a contract, grant, or cooperative agreement (or its prime contractor must have a subcontract) with the person(s) described in paragraph (a) of this SFAR No. 113, § 91.1607, on whose behalf the department, agency, or instrumentality requests FAA approval.

VI. Requests for Exemption

Any operations not conducted under an approval issued by the FAA through the approval process set forth previously must be conducted under an exemption from SFAR No. 113, § 91.1607. A request by any person covered under SFAR No. 113, § 91.1607, for an exemption must comply with 14 CFR part 11, and will require exceptional circumstances beyond those contemplated by the approval process set forth previously. In addition to the information required by 14 CFR 11.81, at a minimum, the requestor must describe in its submission to the FAA—

• The proposed operation(s), including the nature of the operation;
• The service to be provided by the person(s) covered by the SFAR;
• The specific locations in either or both of the Simferopol (UKFV) and Dnipropetrovsk (UKDV) FIRs where the proposed operation(s) will be conducted, including, but not limited to, the flight path and altitude of the aircraft while it is operating in the UKFV and/or UKDV FIRs and the airports, airfields and/or landing zones at which the aircraft will take-off and land); and
• The method by which the operator will obtain current threat information and an explanation of how the operator will integrate this information into all phases of its proposed operations (*e.g.,* the pre-mission planning and briefing, in-flight, and post-flight phases).

Additionally, the release and agreement to indemnify, as referred to previously, will be required as a condition of any exemption that may be issued under SFAR No. 113, § 91.1607.

The FAA recognizes that operations that may be affected by SFAR No. 113, § 91.1607, may be planned for the governments of other countries with the support of the U.S. Government. While these operations will not be permitted through the approval process, the FAA will process exemption requests for such operations on an expedited basis and prior to any private exemption requests.

VII. Regulatory Notices and Analyses

A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Orders 12866 and 13563 direct 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 (Pub. L. 96–354), as codified in 5 U.S.C. 603 *et seq.,* requires agencies to analyze the

economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39), as amended, 19 U.S.C. Chapter 13, prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as codified in 2 U.S.C. Chapter 25, 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 with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

In conducting these analyses, FAA has determined this final rule has benefits that justify its costs. This rule is a significant regulatory action as defined in section 3(f) of Executive Order 12866, as it raises novel policy issues contemplated under that Executive Order; further, this rule is ''significant'' as defined in DOT's Regulatory Policies and Procedures. This rule will not have a significant economic impact on a substantial number of small entities. This rule will not create unnecessary obstacles to the foreign commerce of the United States. This rule will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector by exceeding the threshold identified above.

Department of Transportation (DOT) Order 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits a statement to that effect and the basis for it to be included in the preamble if a full regulatory evaluation of the costs and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows.

This rule extends the existing prohibition against U.S. civil flight operations in the UKFV and UKDV FIRs. As we noted in the most recent previous amendment to SFAR No. 113, § 91.1607 (79 FR 77860, December 29, 2014), almost all U.S. operators already had voluntarily ceased their operations in these FIRs prior to the issuance of the FAA NOTAM on July 18, 2014 (UTC), prohibiting U.S. civil flight operations in these two FIRS in their entirety. Prior to the issuance of the July 18, 2014 (UTC) NOTAM, the FAA had already prohibited U.S. civil flight operations in a portion of the UKFV FIR due to a dispute between Ukraine and the Russian Federation over which country is responsible for providing air navigation services in the area, first via NOTAM and subsequently when the FAA initially published SFAR No. 113, § 91.1607, on April 25, 2014. Consequently, no U.S. operators were operating in that portion of the UKFV FIR at the time of the December 29, 2014 amendment to the rule.

Because of the continuing significant hazards to U.S. civil aviation discussed in the Background section of this final rule, the FAA believes that few, if any, U.S. operators presently wish to conduct operations in either of these two FIRS. Moreover, both the amendment published on December 29, 2014, and this rule, permit a U.S. Government department, agency, or instrumentality to request FAA approval on behalf of a person described in paragraph (a) of SFAR No. 113, § 91.1607, to conduct operations under a contract (or subcontract), grant, or cooperative agreement with that department, agency, or instrumentality. As no U.S. Government department, agency, or instrumentality has requested such approval since December 29, 2014, there is apparently little demand for such approvals. Finally, the possibility of obtaining an approval, should one be requested, lowers the expected cost of the extended rule. Accordingly, the FAA believes the incremental costs of this final rule will be minimal. These minimal costs will be exceeded by the benefits of avoiding the deaths, injuries, and/or property damage that would result from a U.S. operator's aircraft being shot down (or otherwise damaged) while operating in either or both of the UKFV and UKDV FIRs.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis, as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

As described in the Regulatory Evaluation section of this preamble, the incremental costs of this rule are minimal. Therefore, as provided in § 605(b), the head of the FAA certifies that this rulemaking will not result in a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended, prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to this Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

The FAA has assessed the effect of this final rule and determined that its purpose is to protect the safety of U.S. civil aviation from a hazard outside the U.S. Therefore, the rule is in compliance with the Trade Agreements Act.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in

1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $155.0 million in lieu of $100 million.

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there is no new requirement for information collection associated with this immediately adopted final rule.

F. International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to this regulation.

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are 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 has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6f of this order and involves no extraordinary circumstances.

The FAA has reviewed the implementation of this SFAR and determined it is categorically excluded from further environmental review according to FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.6f. The FAA has examined possible extraordinary circumstances and determined that no such circumstances exist. After careful and thorough consideration of the action, the FAA finds that this Federal action does not require preparation of an Environmental Assessment or Environmental Impact Statement in accordance with the requirements of NEPA, Council on Environmental Quality (CEQ) regulations, and FAA Order 1050.1F.

VIII. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this immediately adopted final rule under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this immediately adopted final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it would not be a ''significant energy action'' under the executive order and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, (77 FR 26413, May 4, 2012) promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no effect on international regulatory cooperation.

IX. Additional Information

A. Availability of Rulemaking Documents

An electronic copy of rulemaking documents may be obtained from the Internet by—

- Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);
- Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies* or
- Accessing the Government Publishing Office's Web page at *http://www.fdsys.gov*

Copies may also be obtained by sending a request (identified by docket or amendment number of the rule) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9677.

All documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed from the Internet through the Federal eRulemaking Portal referenced above.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 91

Air traffic control, Aircraft, Airmen, Airports, Aviation safety, Freight, Ukraine.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations, as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 is revised to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 1155, 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, 47534, articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.1607 by revising paragraphs (a)(2), (c), and (e) to read as follows:

§ 91.1607 Special Federal Aviation Regulation No. 113—Prohibition Against Certain Flights in the Simferopol (UKFV) and Dnipropetrovsk (UKDV) Flight Information Regions (FIRs).

(a) * * *

(2) All persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and

* * * * *

(c) *Permitted operations.* This section does not prohibit persons described in paragraph (a) of this section from conducting flight operations in either or both of the Simferopol (UKFV) or Dnipropetrovsk (UKDV) FIRs, provided that such flight operations are conducted under a contract, grant, or cooperative agreement with a department, agency, or instrumentality of the U.S. government (or under a subcontract between the prime contractor of the department, agency, or instrumentality and the person described in paragraph (a) of this section) with the approval of the FAA, or under an exemption issued by the FAA. The FAA will process requests for approval or exemption in a timely manner, with the order of preference being: first, for those operations in support of U.S. government-sponsored activities; second, for those operations in support of government-sponsored activities of a foreign country with the support of a U.S. government department, agency, or instrumentality; and third, for all other operations.

* * * * *

(e) *Expiration.* This SFAR will remain in effect until October 27, 2016. The FAA may amend, rescind, or extend this SFAR as necessary.

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f), 40101(d)(1), 40105(b)(1)(A), and 44701(a)(5), on October 22, 2015.

Michael P. Huerta,

Administrator.

[FR Doc. 2015–27334 Filed 10–22–15; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2015–N–3472]

Medical Devices; Immunology and Microbiology Devices; Classification of Autosomal Recessive Carrier Screening Gene Mutation Detection System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) has classified an autosomal recessive carrier screening gene mutation detection system into class II (special controls). The special controls that apply to this device are identified in this order and will be part of the codified language for the autosomal recessive carrier screening gene mutation detection system classification. The Agency has classified the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective October 27, 2015. The classification was applicable February 19, 2015.

FOR FURTHER INFORMATION CONTACT: Sunita Shukla, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4647, Silver Spring, MD 20993–0002, 301–796–6406.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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), 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 FD&C 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 FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, after receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

23andMe, Inc., submitted a direct de novo request for classification of the 23andMe PGS Carrier Screening Test for Bloom Syndrome under section 513(f)(2)(A)(ii) of the FD&C Act, based on a determination that there is no legally marketed device on which to base a determination of substantial equivalence.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. After review of the information submitted in the de novo request, FDA classified the device into class II because general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, and there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Therefore, on February 19, 2015, FDA issued an order to the requestor classifying the device into class II. The classification of the device will be codified at 21 CFR 866.5940.

The device is assigned the generic name autosomal recessive carrier screening gene mutation detection system, and it is identified as a qualitative in vitro molecular diagnostic system used for genotyping of clinically relevant variants in genomic DNA isolated from human specimens intended for prescription use or over-the-counter use. The device is intended for autosomal recessive disease carrier screening in adults of reproductive age. The device is not intended for copy number variation, cytogenetic, or biochemical testing.