

the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

#### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

#### PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

**Agusta S.p.A.** Docket No. 2003-SW-28-AD.

**Applicability:** Model A109E helicopters, up to and including serial number (S/N) 11150 with Pratt & Whitney Canada, Inc. PW206C engines, and S/N 11501 through 11509 with Turbomeca Arrius TM2K1 engines, with a passenger compartment sliding door (door), part number (P/N) 109-0360-48-101 (left-hand (LH)), P/N 109-0360-48-102 (right-hand (RH)), P/N 109-0360-48-201 (LH), or P/N 109-0360-48-202 (RH), installed, certificated in any category.

**Compliance:** Required within 90 days, unless accomplished previously.

To prevent the inadvertent opening of a door and loss of a passenger or other objects from the cabin, accomplish the following:

(a) Modify the doors by replacing levers, P/N 109-0362-30-103 (LH) and P/N 109-0362-30-104 (RH), and links, P/N 109-0362-05-101; with levers P/N 109-0362-30-109 (LH) and P/N 109-0362-30-110 (RH), and links, P/N 109-0362-05-105, and the

hardware contained in kits, P/N 109-0823-25-101 (LH) and P/N 109-0823-25-102 (RH) in accordance with the Compliance Instructions in Agusta Bollettino Tecnico No. 109 EP-33, dated March 19, 2003.

(b) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Safety Management Group, Rotorcraft Directorate, FAA, for information about previously approved alternative methods of compliance.

**Note:** The subject of this AD is addressed in Ente Nazionale per l'Aviazione Civile (Italy) AD No. 2003-109, dated March 27, 2003.

Issued in Fort Worth, Texas, on October 16, 2003.

**David A. Downey,**

*Manager, Rotorcraft Directorate, Aircraft Certification Service.*

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#### DEPARTMENT OF COMMERCE

#### Bureau of the Census

#### 15 CFR Part 30

[Docket Number 031009254-3254-01]

RIN 0607-AA38

#### Mandatory Automated Export System (AES) Filing for all Shipments Requiring Shipper's Export Declaration Information

**AGENCY:** Bureau of the Census, Commerce.

**ACTION:** Advance notice of proposed rulemaking and request for comments.

**SUMMARY:** The U.S. Census Bureau (Census Bureau) is issuing this advance notice of proposed rulemaking to announce and to solicit comments on the Census Bureau's intent to propose a rule that would make mandatory the filing of all export shipments requiring Shipper's Export Declaration (SED) information on the Automated Export System (AES)/AESDirect. The Census Bureau also requests comment on its intention, subject to agreement with the Bureau of Customs and Border Protection (CBP) and other federal agencies participating in the AES, to modify the AES Option 4 post-departure filing program. The Census Bureau welcomes any comments or concerns regarding the impact of these intended changes on the export community.

**DATES:** Submit written comments regarding this document on or before November 21, 2003.

**ADDRESSES:** Direct all written comments to the Director, U.S. Census Bureau,

Room 2049, Federal Building 3, Washington, DC 20233.

#### FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to C. Harvey Monk, Jr., Chief, Foreign Trade Division, U.S. Census Bureau, Room 2104, Federal Building 3, Washington, DC 20233-6700, (301) 763-2255, by fax (301) 457-2645, or by e-mail [c.harvey.monk,jr@census.gov](mailto:c.harvey.monk,jr@census.gov).

**SUPPLEMENTARY INFORMATION:** The AES is the electronic method to file the information required on the paper SED and the ocean manifest information directly with the CBP. AESDirect is the Census Bureau's free Internet-based system for filing SED information on the AES. Further references to the AES cover both the AES and AESDirect.

Filing on the AES will become mandatory for all export shipments required to be filed under Title 13, United States Code (U.S.C.), Chapter 9. On September 30, 2002, the President signed H.R. 1646 into law (Public Law 107-228). The short title to this law is the Foreign Relations Authorization Act, Fiscal Year 2003. Division B is the Security Assistance Act of 2002. Section 1404—Improvements to the Automated Export System—amends Title 13, U.S.C., Chapter 9.

The AES mandatory electronic filing requirement and penalty authority are set forth in Public Law 107-228. This law directs the Secretary of Commerce, with the concurrence of the Secretary of State and the Secretary of Treasury, to publish regulations in the **Federal Register** requiring, upon the effective date of these regulations, that all persons who are required to file export information under Title 13, U.S.C., Chapter 9, file such information through the AES. The filing of SED information on paper will be eliminated (Option 1). This law also imposes penalties for delayed filings, for failure to file, filing of false or misleading information and for furthering other unlawful activities. A full description of Public Law 107-228, Section 1404, can be found at no cost on the Library of Congress Web site at <http://www.thomas.gov>.

In the future, the Census Bureau will issue proposed and final rules in the **Federal Register**, providing for implementation of the AES mandatory filing requirement and allowing the public to comment. The Census Bureau also will issue regulations regarding imposition of the penalties, both civil and criminal, for the late filing, failure to file, and false filing of export information and furtherance of other illegal activities through the AES. These regulations will provide for

administrative proceedings for imposition of a civil penalty for violation(s) of Public Law 107-228. The authority to enforce penalty provisions of Public Law 107-228 will be delegated to the Office of Export Enforcement of the Bureau of Industry and Security, U.S. Department of Commerce, and/or the U.S. Department of Homeland Security.

In addition, the Census Bureau will address other issues in the forthcoming rulemaking process discussed above. Because the changes discussed above will result in a major revision of the Foreign Trade Statistics Regulations, we plan to use this as an opportunity to improve the regulations' clarity and readability. It is possible that we could make some additional changes to the rules as part of this process.

An additional purpose of this notice is to announce and request comment on the Census Bureau's intention, subject to agreement with the CBP and other federal agencies participating in the AES, to modify the AES Option 4 post-departure filing program. Currently, Option 4 is a method of post-departure filing that considers the trade community's business practices and also provides for an approval process that ensures that only the most compliant companies are approved for this method of filing. With Option 4 privileges, shipment information can be transmitted to the AES no later than ten working days from the date of exportation. (Refer to Foreign Trade Statistics Regulations, title 15, Code of Federal Regulations, part 30, sections 30.61 and 30.62, for information on AES filing Option 4.)

The Census Bureau also has had numerous discussions over the past several months with the trade community and several federal government agencies regarding a proposal to develop and implement the AES Filer Licensing and Permit Program. After consultation both internally and externally, the Census Bureau has decided not to move forward with the development and implementation of an AES filer licensing program concurrently with requiring full mandatory electronic filing of export information through the AES. However, the Census Bureau will continue to explore the need for an AES filer licensing program.

#### Executive Orders

This program notice has been determined to be not significant for

purposes of Executive Order (E.O.) 12866. This notice does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under E.O. 13132.

#### Paperwork Reduction Act

Notwithstanding any other provisions of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), unless that collection of information displays a current valid Office of Management and Budget (OMB) control number. The forthcoming rules will contain a collection of information subject to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). In accordance with the PRA, this collection of information will be submitted to OMB for approval.

#### Program Change

The actual effective date of full AES mandatory filing requirements and implementation of the penalty provision regarding mandatory filing are dependent upon the publication and implementation of final regulatory amendments by the Census Bureau. Proposed and final rules defining the regulatory revisions that will be made to implement the legislation will be published in the **Federal Register**, as discussed above.

Dated: October 16, 2003.

**Charles Louis Kincannon**,  
Director, Bureau of the Census.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 310 and 334

[Docket No. 1978N-036L]

RIN 0910-AA01

#### Laxative Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; reopening of the administrative record.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until January 20, 2004, the administrative record for the rulemaking for over-the-counter (OTC) laxative drug products to accept comments and data concerning these drug products that have been filed with FDA's Division of Dockets Management, because the administrative record officially closed at various times during the course of this rulemaking. The administrative record will remain open until January 20, 2004, to allow for public comment on the comments and data being accepted into the rulemaking at this time. This action is part of FDA's ongoing review of OTC drug products.

**DATES:** Submit written or electronic comments and data by January 20, 2004.

**ADDRESSES:** Submit written comments and data 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:** Mary S. Robinson, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA has, on numerous occasions, received new data and information bearing on OTC drug panel reports and proposed monographs after the closing of the administrative record in a rulemaking proceeding. Under § 330.10(a)(7)(iii) (21 CFR 330.10(a)(7)(iii)), new data and information may be submitted within 12 months after publication of a tentative final monograph (TFM). Within 60 days after this 12-month period ends, comments on the new data and information may be submitted (see § 330.10(a)(7)(iv)). Under § 330.10(a)(10)(i), the administrative record closes at the end of this 60-day period.

FDA published a TFM on laxative drug products for OTC human use on January 15, 1985 (50 FR 2124). On a number of occasions since the TFM was published, FDA reopened the administrative record for this rulemaking for various reasons. (See table 1 of this document for reopening dates and reasons.)