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**List of Subjects in 18 CFR Part 385**

Administrative practice and procedure, Electric power, Penalties, Pipelines, and Reporting and recordkeeping requirements.

By the Commission.

**Linwood A. Watson, Jr.**,  
*Acting Secretary.*

In consideration of the foregoing, the Commission amends part 385, Chapter I, Title 18, *Code of Federal Regulations*, as follows.

**PART 385—RULES OF PRACTICE AND PROCEDURE**

1. The authority citation continues to read as follows:

**Authority:** 5 U.S.C. 551-557; 15 U.S.C. 717-717z, 3301-3432; 16 U.S.C. 791a-825r, 2601-2645; 31 U.S.C. 9701; 42 U.S.C. 7101-7352; 49 U.S.C. 60502; 49 App. U.S.C. 1-85 (1988).

**§ 385.2201 Rules governing off-the-record communications. (Rule 2201).**

\* \* \* \* \*

2. In § 385.2201 paragraphs (e)(1)(viii) and (g)(3) are added to read as follows:

(e) *Exempt off-the-record communications.* (1) \* \* \*

(viii) An off-the-record communication from any person related to any national security-related issue concerning a facility regulated by the Commission or a facility that provides Commission-regulated services.

\* \* \* \* \*

(g) *Disclosure of exempt off-the-record communications.* \* \* \*

(3) Any document, or a summary of the substance of any oral communications, obtained through an exempt off-the-record communication

under paragraphs (e)(1)(viii) of this section, will be submitted promptly to the Secretary and placed in a non-public decisional file of the relevant Commission proceeding and made available to parties to the proceeding, subject to their signing a non-disclosure agreement. Responses will also be placed in the non-public decisional file and held confidential. If the Commission determines that the communication does not contain sensitive national security-related information, it will be placed in the decisional file.

\* \* \* \* \*

[FR Doc. 01-32068 Filed 12-28-01; 8:45 am]

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**DEPARTMENT OF THE TREASURY**

**Customs Service**

**19 CFR Parts 122 and 178**

[T.D. 02-01]

**RIN 1515-AC99**

**Passenger and Crew Manifests Required for Passenger Flights in Foreign Air Transportation to the United States**

**AGENCY:** U.S. Customs Service, Department of the Treasury.

**ACTION:** Interim rule; solicitation of comments.

**SUMMARY:** This document amends the Customs Regulations, on an interim basis, in order to implement a provision of the Aviation and Transportation Security Act which requires that each air carrier, foreign and domestic, operating a passenger flight in foreign air transportation to the United States electronically transmit to Customs in advance of arrival a passenger and crew manifest that contains certain specified information. The submission of this information to Customs is required for purposes of ensuring aviation safety and protecting national security.

**DATES:** Interim rule is effective December 31, 2001. Comments must be received on or before March 1, 2002.

**ADDRESSES:** Written comments may be addressed to and inspected at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, NW., 3rd Floor, Washington, DC 20229.

**FOR FURTHER INFORMATION CONTACT:** For legal matters: Larry L. Burton, Office of Regulations and Rulings, 202-927-1287;

For operational matters: James Jeffers, Office of Field Operations, 202-927-4444.

**SUPPLEMENTARY INFORMATION:**

**Background**

On November 19, 2001, the President signed into law the Aviation and Transportation Security Act (Act), Public Law 107-71. Section 115 of that law amended 49 U.S.C. 44909, to add a new paragraph (c) in order to provide that, not later than 60 days after the date of enactment of the Act, each air carrier, foreign and domestic, operating a passenger flight in foreign air transportation to the United States must electronically transmit to Customs a passenger and crew manifest containing certain information in advance of arrival. Under this statutory provision, the transmission of passenger and crew manifest information will be required even for flights where the passengers and crew have already been pre-inspected or pre-cleared at the foreign location for admission to the United States.

Specifically, under 49 U.S.C. 44909(c)(2)(A)-(E), for each passenger and crew manifest relating to a passenger flight in foreign air transportation to the United States, the following information is required to be submitted to Customs: The full name of each passenger and crew member; the date of birth and citizenship of each passenger and crew member; the gender of each passenger and crew member; the passport number and country of issuance of the passport of each passenger and crew member if a passport is required for travel; and the United States visa number or resident alien card number of each passenger and crew member, as applicable.

In addition, under 49 U.S.C. 44909(c)(2)(F), such other information concerning passenger and crew manifests may be required to be transmitted to Customs, as may be determined to be reasonably necessary to ensure aviation safety.

Moreover, the statute provides that the electronic transmission of a passenger and crew manifest required for a covered flight must be received by Customs in advance of the aircraft landing in the United States in such manner, time and form as Customs may prescribe (49 U.S.C. 44909(c)(4)).

**Passenger Manifest; Crew Manifest**

This document amends the Customs Regulations to implement 49 U.S.C. 44909(c)(2)(A)-(E) in a new § 122.49a. This section requires air carriers, for each flight subject to the statute, to

transmit to Customs, by means of an electronic data interchange system that is approved by Customs, a passenger manifest and, by way of a separate transmission using the same system, a crew manifest. (The system currently in effect for this purpose is called the Advance Passenger Information System (APIS)). Furthermore, the air carrier must transmit each manifest so that the crew manifest is received by Customs electronically in advance of departure from the last foreign port or place, and the passenger manifest is received not later than 15 minutes after the departure of the aircraft from the last foreign port or place (after the wheels are up on the aircraft and the aircraft is directly en route to the United States). To distinguish the two manifests transmitted for a given flight, the crew manifest must have the alpha character "C" included in the transmission to denote that the manifest information pertains to the crew members for the flight.

#### **Required Data Elements for the Manifests**

The following data elements comprising the passenger and crew manifests for each flight under 49 U.S.C. 44909(c) must be electronically transmitted to Customs:

(1) The International Air Transport Authority (IATA) airline code; the flight number (followed by the alpha character "C" in the case of the message transmitting the crew manifest for the flight); the departure location IATA code; the U.S. arrival location(s) IATA code(s); the date of flight arrival; and whether each passenger and crew member on the flight is destined for the U.S. or in transit through the U.S.;

(2) The full name of each passenger and crew member; the date of birth and citizenship of each passenger and crew member; the gender of each passenger and crew member; the passport number and country of issuance of the passport of each passenger and crew member if required for travel; and the United States visa number or resident alien card number of each passenger and crew member, as applicable; and

(3) The foreign airport where each passenger began his air transportation to the United States; for each passenger and crew member destined for the United States, the airport in the United States where the passenger and crew member will process through Customs and Immigration formalities; and for each passenger and crew member transiting through the United States and not clearing through Customs and Immigration formalities, the foreign

airport of final destination for the passenger and crew member.

Many of the data elements contained in item "2" above describing each passenger and crew member on a flight are contained in travel documents that air carriers review prior to the boarding of the passenger. Air carriers are to transmit the data elements listed in item "2" above, by transmitting electronically to Customs one, and only one, travel document, selected in the following order of preference: U.S. Alien Registration Card; U.S. Border Crossing Card; U.S. non-immigrant visa; a U.S. Refugee Travel Document or Re-Entry Permit; U.S. Passport; or non-U.S. passport.

Even though Customs recognizes that the travel document information being transmitted to Customs by the air carrier may not contain all the informational elements required by the statute and set forth in the regulations, Customs' timely receipt of the electronic transmission of the preferred travel document pertaining to each passenger or crew member for a particular flight will at the present time be considered as constituting full compliance with the informational requirements of 49 U.S.C. 44909(c)(2)(A)-(E). Air carriers will be required to transmit any informational elements required by the statute and this regulation which are not contained in transmitted travel documents by a date that will be announced in a future **Federal Register** document.

It is further observed that the data elements contained in passenger and crew manifests for flights subject to 49 U.S.C. 44909(c)(1) that are received by Customs electronically may, upon request, be shared with other Federal agencies for the purpose of protecting national security (49 U.S.C. 44909(c)(5)).

Lastly, it is noted that the requirement in 49 U.S.C. 44909(c)(3) that carriers make passenger name record information available to Customs upon request will be the subject of a separate document published in the **Federal Register**.

#### **Comments**

Before adopting this interim regulation as a final rule, consideration will be given to any written comments that are timely submitted to Customs. Customs specifically requests comments on the clarity of this interim rule and how it may be made easier to understand. Comments submitted will be available for inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on

regular business days between the hours of 9:00 a.m. and 4:30 p.m. at the Regulations Branch, U.S. Customs Service, 1300 Pennsylvania Avenue, NW., 3rd Floor, Washington, DC.

#### **Administrative Procedure Act, Executive Order 12866 and the Regulatory Flexibility Act**

This interim regulation has been determined to be critically necessary for purposes of ensuring aviation safety and protecting national security. Further, Congress has directed air carriers to comply no later than 60 days from enactment of the Aviation and Transportation Security Act. For these reasons, Customs finds that good cause exists in this case for dispensing with the notice and public comment procedures of the Administrative Procedure Act (5 U.S.C. 553) as being contrary to the public interest pursuant to 5 U.S.C. 553(b)(B), and, in this connection, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required. Because this document is not subject to the requirements of 5 U.S.C. 553, as noted, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Nor does the interim regulation result in a "significant regulatory action" under E.O. 12866.

#### **Paperwork Reduction Act**

This interim regulation is being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information contained in this interim regulation has been reviewed and, pending the receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) under control number 1515-0232. An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

The collection of information required in this document is contained in § 122.49a. This information is required in connection with passenger flights in foreign air transportation to the United States. The likely respondents and/or recordkeepers are business organizations, specifically air carriers, including foreign air carriers.

*Estimated total annual reporting and/or recordkeeping burden:* 2,380 hours.

*Estimated average annual burden per respondent/recordkeeper:* .0028 hours.

*Estimated number of respondents and/or recordkeepers:* 200.

*Estimated annual frequency of responses:* 850,000.

Comments on the collection of information should be sent to the Office of Management and Budget, Attention: Desk Officer of the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. A copy should also be sent to the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, NW., 3rd Floor, Washington, DC 20229. Comments should be submitted within the same time frame that comments are due regarding the substance of the interim regulation.

Comments are invited on: (a) Whether the collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or startup costs and costs of operations, maintenance, and purchase of services to provide information.

Part 178, Customs Regulations (19 CFR part 178), containing the list of approved information collections, is appropriately revised to make provision for this information collection.

#### List of Subjects

##### 19 CFR Part 122

Air carriers, Aircraft, Airports, Air transportation, Customs duties and inspection, Entry procedure, Reporting and recordkeeping requirements, Security measures.

##### 19 CFR Part 178

Administrative practice and procedure, Collections of information, Paperwork requirements, Reporting and recordkeeping requirements.

#### Amendments to the Regulations

Parts 122 and 178, Customs Regulations (19 CFR parts 122 and 178), are amended as set forth below.

#### PART 122—AIR COMMERCE REGULATIONS

1. The authority citation for part 122 continues to read, and a specific sectional authority citation is added to read, as follows:

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

§ 122.49a also issued under 19 U.S.C. 1431 and 49 U.S.C. 44909(c).

2. Subpart E of part 122 is amended by adding § 122.49a to read as follows:

##### § 122.49a Passenger and crew manifests.

(a) *General requirement.* Each air carrier, foreign and domestic, operating a passenger flight in foreign air transportation to the United States, including flights where the passengers and crew have already been pre-inspected or pre-cleared at the foreign location for admission to the United States, must transmit to Customs a passenger manifest and a crew manifest containing the information set forth in paragraph (c) of this section, as required by 49 U.S.C. 44909(c)(1). The electronic transmission of manifest information must be effected through an electronic data interchange system approved by Customs. This information must be transmitted to the U.S. Customs Data Center, Customs Headquarters.

(b) *Passenger and crew manifests separately transmitted; advance receipt by Customs.* For each flight subject to paragraph (a) of this section, the air carrier must separately transmit to Customs the passenger manifest and the crew manifest. The crew manifest must be received in advance of departure from the last foreign port or place. The passenger manifest must be received by Customs no later than 15 minutes after the flight has departed from the last foreign port or place (after the wheels are up on the aircraft and the aircraft is en route directly to the United States).

(c) *Information required—(1) Airline and flight information.* For each passenger manifest and crew manifest relating to a flight falling within the scope of paragraph (a) of this section, the following airline and flight information must be electronically transmitted to Customs: the airline IATA (International Air Transport Authority) code; the flight number (followed by the alpha character "C" in the case of the crew manifest for the flight); the departure location IATA code; the U.S. arrival location(s) IATA code(s); the date of flight arrival in the United States; and whether each passenger and crew member on the flight is destined for the U.S. or in transit through the U.S.

(2) *Identifying information for each passenger or crew member.* In the manner prescribed in paragraph (c)(3) of this section, for each passenger manifest and crew manifest, as applicable, that relates to a flight falling within the scope of paragraph (a) of this section,

the following information that identifies each passenger and crew member on the flight must be electronically transmitted to Customs: The full name of each passenger and crew member; the date of birth and citizenship of each passenger and crew member; the gender of each passenger and crew member; the passport number and country of issuance of the passport of each passenger and crew member if a passport is required for travel; and the United States visa number or resident alien card number of each passenger and crew member, as applicable (49 U.S.C. 44909(c)(2)(A)–(E)).

(3) *Use of travel document to obtain data.* Air carriers are to provide the data elements set out in paragraph (c)(2) of this section that describe each passenger and crew member on a flight subject to paragraph (a) of this section by transmitting to Customs one, and only one, travel document per passenger or crew member, selected in the following order of preference: U.S. Alien Registration Card; U.S. Border Crossing Card; U.S. non-immigrant visa; U.S. Refugee Travel Document or Re-Entry Permit; U.S. Passport; or non-U.S. passport. Customs timely receipt of the electronic transmission of the preferred travel document pertaining to a passenger or crew member for a covered flight will be considered as constituting full compliance with the informational requirements of 49 U.S.C. 44909(c)(2)(A)–(E), subject to paragraph (c)(5) of this section.

(4) *Additional information required; travel itinerary of each passenger and crew member.* In addition, for each passenger manifest and crew manifest, as applicable, that relates to a flight falling within the scope of paragraph (a) of this section, air carriers are required to transmit for each passenger and crew member, the foreign airport where they began their air transportation to the United States. Also, for passengers and crew members destined for the United States, the air carrier must designate the airport in the United States where the passenger will be processed through Customs and Immigration formalities. Likewise, for passengers and crew members that are transiting through the United States and not clearing Customs and Immigration formalities, the air carrier bringing them into the United States must transmit the foreign airport of ultimate destination.

(5) *Receipt of all required data elements.* Air carriers will be required to transmit any informational elements required by paragraph (c) of this section which are not contained in the transmitted travel documents by a date

that will be announced in the **Federal Register**.

(d) *Carrier responsibility for comparing information collected with travel document.* The carrier collecting the information described in paragraph (c)(2) of this section is responsible for comparing this information with the related travel document under paragraph (c)(3) of this section, in order to ensure that the information is correct, that the document appears to be valid for travel to the United States, and that the passenger or crew member, as applicable, is the person to whom the travel document was issued.

(e) *Sharing of manifest information with other Federal agencies.* Information contained in passenger and crew manifests for flights subject to paragraph (a) of this section (49 U.S.C. 44909(c)(1)) that is received by Customs electronically may, upon request, be shared with other Federal agencies for the purpose of protecting national security (49 U.S.C. 44909(c)(5)).

#### **PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS**

1. The authority citation for part 178 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 *et seq.*

2. Section 178.2 is amended by adding the following in appropriate numerical sequence according to the section number under the columns indicated:

##### **§ 178.2 Listing of OMB control numbers.**

19 CFR section	Description	OMB control no.
*	*	*
§ 122.49a	Passenger and crew manifests.	1515-0232
*	*	*

Approved: December 21, 2001.

**Robert C. Bonner,**

*Commissioner of Customs.*

**Timothy E. Skud,**

*Acting Deputy Assistant Secretary of the Treasury.*

[FR Doc. 01-32034 Filed 12-28-01; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 352**

**[Docket No. 78N-0038]**

**RIN 0910-AA01**

#### **Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Partial Stay; Final Rule**

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

**ACTION:** Final rule; partial stay.

**SUMMARY:** The Food and Drug Administration (FDA) is staying the final monograph for over-the-counter (OTC) sunscreen drug products that published in the **Federal Register** of May 21, 1999 (64 FR 27666). The final monograph established conditions under which OTC sunscreen drug products are generally recognized as safe and effective and not misbranded. This stay of effective date applies to all OTC sunscreen drug products that would be regulated under part 352 (21 CFR part 352). This action does not stay the effective date for products that would be regulated under parts 310 and 700 (21 CFR parts 310 and 700). This action is being taken because the agency will be amending part 352 to address formulation, labeling, and testing requirements for both ultraviolet A (UVA) radiation protection and ultraviolet B (UVB) radiation protection. This action is part of FDA's ongoing review of OTC drug products.

**DATES:** This rule is effective January 30, 2002. Part 352, added at 64 FR 27666 at 27687, is stayed until further notice. Written or electronic comments by April 1, 2002.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (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:** Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2307.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of May 21, 1999, FDA published a final rule in the form of a final monograph for OTC sunscreen drug products in part 352. The monograph included 16 active

ingredients, required labeling for products that contain one or more of these active ingredients, a standardized test for measuring sun protection factor (SPF) values, and standard methods for measuring the water resistant properties of sunscreens. The labeling and test methods covered products intended to provide UVB radiation protection. The monograph did not, however, address active ingredients, labeling, and test methods for products intended to provide UVA protection. The final rule also included related nonmonograph conditions in § 310.545(a)(29) (21 CFR 310.545(a)(29)) and new § 700.35 (21 CFR 700.35), which addressed labeling for cosmetic products that contain sunscreen active ingredients for nontherapeutic, nonphysiologic uses (e.g., as a color additive or to protect the color of the product). The agency set a 2-year effective date (May 21, 2001) for part 352 and for §§ 310.545(a)(29) and 700.35.

In the **Federal Register** of June 8, 2000 (65 FR 36319), the agency extended the effective date for all OTC sunscreen drug and cosmetic products that would be regulated under parts 310, 352, and 700 to December 31, 2002. The agency stated that this extension would be in the public interest as the agency developed a comprehensive sunscreen final monograph that addresses formulation, labeling, and testing requirements for both UVB and UVA radiation protection under part 352. The agency stated in this notice that it intended to move forward and publish a proposed rule for a comprehensive final monograph, receive comments on that proposal, and issue a final rule by December 31, 2001. That final rule would then have a 1-year effective date of December 31, 2002.

##### **II. Stay of Part 352**

The June 8, 2000, extension of effective date also included a reopening of the administrative record to allow for comment on specific information the agency requested in that document. The comment period closed on September 6, 2000. Since that time, the agency has been developing a proposed amendment to part 352 that addresses both UVB and UVA radiation protection.

The agency expects to publish the proposal to amend part 352 next year. Following that publication, there will be a comment period and then the agency will prepare an amended final monograph for publication in a future issue of the **Federal Register**. Because the agency has not yet published the proposed amendment to part 352, it is not possible for manufacturers of OTC sunscreen drug products to relabel and