

related to the subject presented above, the FAA has determined that air safety and the public interest require adoption of the rule. The FAA has determined that this correction will not change the meaning of the action nor add any additional burden on the public beyond that already published. This action corrects the error in the coordinates of the Fredericktown Regional Airport ARP and Farmington VORTAC and confirms the effective date to the direct final rule.

The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on April 20, 2000. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

#### **Correction to the Direct Final Rule**

Accordingly, pursuant to the authority delegated to me, coordinates for the Fredericktown Regional Airport ARP and the Farmington VORTAC as published in the **Federal Register** on December 29, 1999 (64 FR 72924), (**Federal Register** Document 99-33795; page 72925, column one) are corrected as follows:

##### **§ 71.1 [Corrected]**

##### **ACE MO E5 Fredericktown, MO [Corrected]**

On page 72925, in the first column, after Fredericktown Regional Airport, MO, correct the coordinates by removing (lat. 37°36'20" N., long. 90°17'14" W.) and substituting (lat. 37°36'21" N., long. 90°17'14" W.)

On page 72925, in the first column, after Farmington VORTAC correct the coordinates by removing (lat. 37°40'25" N., long. 90°14'02" W.) and substituting (lat. 37°40'24" N., long. 90°14'03" W.)

Issued in Kansas City, MO on February 15, 2000.

**Herman J. Lyons, Jr.,**

*Manager, Air Traffic Division, Central Region.*  
[FR Doc. 00-4748 Filed 2-28-00; 8:45 am]

**BILLING CODE 4910-13-M**

<b>DEPARTMENT OF TRANSPORTATION</b>	<b>DEPARTMENT OF THE TREASURY</b>
<b>Federal Aviation Administration</b>	<b>Customs Service</b>
<b>14 CFR Part 71</b>	<b>19 CFR Parts 12 and 178</b>
[Airspace Docket No. 99-ACE-50]	[T.D. 00-13] <b>RIN 1515-AC04</b>
<b>Amendment to Class E Airspace; Iowa City, IA</b>	<b>Importation of Chemicals Subject to the Toxic Substances Control Act</b>
<b>AGENCY:</b> Federal Aviation Administration, DOT.	<b>AGENCY:</b> Customs Service, Department of the Treasury.
<b>ACTION:</b> Direct final rule; confirmation of effective date.	<b>ACTION:</b> Final rule.
<b>SUMMARY:</b> This document confirms the effective date of a direct final rule which revises Class E airspace at Iowa City, IA.	<b>SUMMARY:</b> This document sets forth final amendments to the Customs Regulations regarding submission of an importer's certification in connection with the importation of chemical substances subject to the Toxic Substances Control Act. The regulatory amendments reduce the regulatory burden by permitting use of a blanket certification for multiple shipments in lieu of a separate certification for each individual shipment. The final regulations also continue the present practice of allowing some flexibility regarding presentation of the required certification with the entry documentation for an individual shipment.
<b>DATES:</b> The direct final rule published at 64 FR 72926 is effective on 0901 UTC, April 20, 2000.	<b>EFFECTIVE DATE:</b> March 30, 2000.
<b>FOR FURTHER INFORMATION CONTACT:</b> Brenda Mumper, Air Traffic Division, Airspace Branch, ACE-520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329-2524.	<b>FOR FURTHER INFORMATION CONTACT:</b> Brad Lund, Office of Field Operations (202-927-0192).
<b>SUPPLEMENTARY INFORMATION:</b> The FAA published this direct final rule with a request for comments in the <b>Federal Register</b> on December 29, 1999 (64 FR 72926). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on April 20, 2000. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.	<b>SUPPLEMENTARY INFORMATION:</b> <b>Background</b> The Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 <i>et seq.</i> ) was enacted by Congress, among other things, to protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances. Section 13 of Title I of the TSCA (15 U.S.C. 2612) governs the entry of those chemical substances into the customs territory of the United States and authorizes the Secretary of the Treasury to refuse entry of any chemical substance that (1) Fails to comply with any rule in effect under the TSCA or (2) is offered for entry in violation of section 5 or 6 of Title I (15 U.S.C. 2604 or 2605) or Title IV (15 U.S.C. 2681 <i>et seq.</i> ) or in violation of a rule or order under section 5 or 6 or Title IV or in violation of an order issued in a civil action brought under section 5 or under section 7 of Title I (15 U.S.C. 2606) or under Title IV. Section 13 also sets forth procedural and other requirements in connection with an entry refusal and authorizes the Secretary of the Treasury, after consultation with the Administrator of the Environmental Protection Agency

(EPA), to issue rules for the administration of section 13.

The regulations implementing section 13 are contained in §§ 12.118–12.127 of the Customs Regulations (19 CFR 12.118–12.127). Within those regulations, § 12.121 concerns reporting requirements. Paragraph (a) of that section covers chemical substances imported in bulk or as part of a mixture and provides for submission of a signed certification by the importer or his authorized agent stating, in the alternative, (1) That all chemical substances in the shipment comply with all applicable rules or orders under the TSCA and that the importer is not offering a chemical substance for entry in violation of the TSCA or any rule or order thereunder (a positive certification) or (2) that all chemicals in the shipment are not subject to the TSCA (a negative certification). Paragraph (a) further requires that the certification be filed with the director of the port of entry before release of the shipment and provides that the certification may appear as a typed or stamped statement (1) on the entry document or commercial invoice, or on a preprinted attachment to the entry document or commercial invoice, or (2) in the case of a release under a special permit for an immediate delivery under § 142.21 of the Customs Regulations (19 CFR 142.21) or in the case of an entry under § 142.3 of the Customs Regulations (19 CFR 142.3), on the commercial invoice or an attachment to the commercial invoice. Paragraph (b) of § 12.121 provides that the provisions of paragraph (a) apply to a chemical substance or mixture as part of an article only if required by a rule or order under the TSCA. Paragraph (c) of that section provides that a certification under paragraph (a) may be signed by means of an authorized facsimile signature.

On January 9, 1990, Customs published a notice of proposed rulemaking in the **Federal Register** (55 FR 738) to amend § 12.121. The proposed amendments included the following changes to paragraph (a): (1) To provide for placement of the typed or stamped certification statement only on the invoice used in connection with the entry and entry summary procedures (and, thus, no longer on the entry document or on an attachment to the entry document or commercial invoice); and (2) in the case of entries or entry summaries processed electronically, to provide for a certification statement in the form of a certification code transmitted as part of the Automated Broker Interface (ABI) transmission. In addition, in order to simplify procedures for importers who

regularly import chemicals, it was proposed to add a new paragraph (b) to permit the use of “blanket” certifications, with a consequential redesignation of present paragraphs (b) and (c) as (c) and (d), respectively. Finally, it was proposed to make a conforming change to newly redesignated paragraph (c), consisting of the addition of a reference to new paragraph (b). The notice solicited comments from the public on the proposals, and the public comment period closed on March 12, 1990. On January 22, 1990, Customs published in the **Federal Register** (55 FR 2100) a correction document setting forth, with regard to the proposed blanket certification procedure, a statement regarding collection of information review requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)).

#### Discussion of Comments

A total of 19 commenters responded to the solicitation of comments in the January 9, 1990, notice. A summary of the submitted comments, and the Customs responses to those comments, are set forth below.

*Comment:* Thirteen commenters were opposed to the proposal regarding inclusion of the certification only on the commercial invoice, and two commenters were in favor of that proposal. Comments against the proposal cited the procedural burden and inefficiency that would result from the proposed restriction, particularly in view of the unavailability of the original invoice for some shipments, the lack of sufficient space on the invoice, the need for a separate certification document in order to avoid delays in the case of air shipments, express consignment shipments and shipments from contiguous countries, and the lack of control by the importer of record where the certification is placed on the invoice by another party.

*Customs response:* The proposal in question was not intended to increase the regulatory burden or to have any of the other adverse effects cited by these commenters. Based on the submitted comments and as a result of further review of this matter, including consultation with the EPA which raised the issue that the proposal was intended to address, Customs has determined that it would be preferable to maintain the status quo under which the importer has the option of including the certification on the commercial invoice or on the entry document or on an attachment to the commercial invoice or entry document. Accordingly, the text of § 12.121, as set forth below, continues to

reflect the substance of the current regulatory text in this regard.

*Comment:* One commenter requested that the TSCA certification be made a requirement for the entry summary rather than a condition of entry.

*Customs response:* As indicated above, the TSCA refers specifically to the “entry” of chemical substances into the Customs territory of the United States. Given the wording of the statute and the clear purpose of the TSCA, which is to protect the health and safety of the general public, the regulation in question must apply for admissibility purposes (that is, when a determination is made as to whether the imported merchandise may be released from Customs custody into the commerce of the United States) rather than in connection with a subsequent filing of the entry summary. Accordingly, the suggestion of this commenter should not be adopted.

*Comment:* Ten commenters specifically supported the proposed blanket certification procedure, four commenters were against it, and two commenters stated that the blanket certification should be optional rather than mandatory. Of the four commenters against the proposal, two commenters argued that a blanket procedure is not feasible where imported mixtures are involved because changes in the chemical composition of a product prior to export could render the blanket certification inaccurate. The other two commenters stated that the proposal would not work in practice because it does not provide for nationwide acceptance of the blanket certification but rather requires separate approval at the local level.

*Customs response:* While it is true that changes in the composition of an imported product could negate the applicability of a previously approved blanket certification, Customs notes that the importer of record is always responsible for ascertaining the true facts regarding an individual import transaction, including for purposes of deciding whether it would be appropriate to rely on a blanket certification on file with Customs. With regard to the lack of provision for nationwide acceptance of a blanket approval, Customs remains of the view that, for operational purposes, approval must take place at the local port level.

Customs believes that the significant number of favorable comments supports the appropriateness of the blanket certification procedure which was intended to simplify procedures and thus reduce the overall regulatory burden on the importing public. Accordingly, § 12.121, as set forth

below, incorporates the proposed blanket certification procedure.

With regard to the optional versus mandatory issue, Customs believes that the regulatory text clearly gives the importer the option (and thus does not impose a requirement) of using the blanket certification procedure, subject only to the port director's exercise of his discretion in accepting the blanket certification.

**Comment:** Three commenters proposed elimination of the TSCA certification for merchandise subject to FDA 701 requirements and for pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as exempted in section 3 of the TSCA and identified in the EPA publication "Toxic Substances Control Act, A Guide for Chemical Importers/Exporters."

**Customs response:** Customs has been advised by EPA that the Guide referred to by these commenters provides that articles as defined in the Guide and tobacco and tobacco products do not require a certification but that food items and pesticides require a negative certification, and EPA also suggested to Customs that the Guide would become confusing in the step-by-step instructions for importers if the negative certification for food items and pesticides were to be eliminated. Moreover, while EPA advised Customs that a negative certification would not be needed if the shipment is accompanied by the appropriate form identifying the merchandise as a pesticide or as a food, food additive, drug, cosmetic or device, as is suggested in the Guide, Customs notes that this approach would not appreciably reduce the regulatory burden on importers. Accordingly, Customs believes that the suggestions of these commenters should not be adopted.

**Comment:** Seven commenters requested that the regulatory text provide for a waiver of the certification requirement for small shipments, samples, low value shipments, mail shipments, and shipments imported for research and development purposes.

**Customs response:** The EPA has advised Customs that automatic waivers of the certification requirement should not be provided for in the regulatory text because authority to grant waivers must remain with the EPA for consideration on a case-by-case basis; the Guide referred to in the preceding comment discussion sets forth the procedures applicable to the issuance of such waivers by the EPA. Therefore, the suggestion of these commenters should not be adopted.

### Other Changes to the Regulatory Texts

In addition to the changes to the proposed regulatory text discussed above in connection with the public comments, Customs has determined that a number of other changes should be made both to the proposed text and to the present § 12.121 text based on further internal review. The principal additional change involves removal of the proposed new language dealing with entries or entry summaries processed electronically: On reconsidering this proposed text, Customs has concluded that it is generally preferable not to set forth specific electronic procedures in a narrow regulatory context but rather to cover them in the context of overall electronic procedures as those procedures are developed and implemented. In addition, the structure of the paragraphs under § 12.121 has been modified without change in substance by setting forth the basic certification requirement in new paragraph (a)(1) and by covering all filing procedures (including the blanket procedure which operates as an exception to the normal entry-by-entry filing procedure) in new paragraph (a)(2). Also, language has been included in the introductory paragraph of the blanket text to clarify that use of the blanket procedure is permissible only for an imported product that conforms to the product description contained in the blanket certification filed with Customs. Finally, a number of editorial, nonsubstantive changes have been made to enhance the clarity of the regulatory text.

### Conclusion

Accordingly, based on the comments received and the analysis of those comments and based on the additional considerations as discussed above, Customs believes that the proposed regulatory amendments should be adopted as a final rule with certain changes as discussed above and set forth below. As a consequence of the adoption of these substantive regulatory amendments, this document also includes an appropriate update of the list of information collection approvals contained in § 178.2 of the Customs Regulations (19 CFR 178.2).

### Executive Order 12866

This document does not meet the criteria for a "significant regulatory action" as specified in E.O. 12866.

### Regulatory Flexibility Act

Pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that the amendments will not have a significant

economic impact on a substantial number of small entities because the amendments are specifically directed toward a reduction of the regulatory burden on the public. Accordingly, the amendments are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

### Paperwork Reduction Act

The collection of information contained in this final rule has been reviewed and approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1515-0173. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

The collection of information in this final rule is in § 12.121. This information is required in connection with importations of chemical substances under the Toxic Substances Control Act (TSCA) and will be used by the U.S. Customs Service to verify compliance with TSCA requirements on imported chemicals. The likely respondents are business organizations including importers, exporters and manufacturers.

The estimated average annual burden associated with the collection of information in this final rule is 2 minutes per respondent or recordkeeper. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the U.S. Customs Service, Information Services Group, Office of Finance, 1300 Pennsylvania Avenue, NW, Washington, DC 20229, and to OMB, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

**Drafting Information.** The principal author of this document was Francis W. Foote, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

### List of Subjects

#### 19 CFR Part 12

Customs duties and inspection, Labeling, Marking, Reporting and recordkeeping requirements.

#### 19 CFR Part 178

Administrative practice and procedure, Exports, Imports, Reporting and recordkeeping requirements.

## Amendments to the Regulations

Accordingly, for the reasons stated in the preamble, Parts 12 and 178, Customs Regulations (19 CFR Parts 12 and 178), are amended as set forth below.

### PART 12—SPECIAL CLASSES OF MERCHANDISE

1. The authority citation for Part 12 continues to read in part as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

\* \* \* \* \*

Sections 12.118 through 12.127 also issued under 15 U.S.C. 2601 *et seq.*;

\* \* \* \* \*

2. Section 12.121 is revised to read as follows:

#### § 12.121 Reporting requirements.

(a) *Chemical substances in bulk or mixtures*—(1) *Certification required.* The importer of a chemical substance imported in bulk or as part of a mixture, or the authorized agent of such an importer, must certify either that the chemical shipment is subject to TSCA and complies with all applicable rules and orders thereunder, or that the chemical shipment is not subject to TSCA, by signing and filing with Customs one of the following statements:

I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order thereunder.

I certify that all chemical substances in this shipment are not subject to TSCA.

(2) *Filing of certification*—(i) *General.* The appropriate certification required under paragraph (a)(1) of this section must be filed with the director of the port of entry before release of the shipment and, except when a blanket certification is on file as provided for in paragraph (a)(2)(ii) of this section, must appear as a typed or stamped statement:

(A) On an appropriate entry document or commercial invoice or on an attachment to that entry document or invoice; or

(B) In the event of release under a special permit for an immediate delivery as provided for in § 142.21 of this chapter or in the case of an entry as provided for in § 142.3 of this chapter, on the commercial invoice or on an attachment to that invoice.

(ii) *Blanket certifications.* A port director may, in his discretion, approve

an importer's use of a "blanket" certification, in lieu of filing a separate certification for each chemical shipment, for any chemical shipment that conforms to a product description provided to Customs pursuant to paragraph (a)(2)(ii)(A) of this section. In approving the use of a "blanket" certification, the port director should consider the reliability of the importer and Customs broker. Approval and use of a "blanket" certification will be subject to the following conditions:

(A) A "blanket" certification must be filed with the port director on the letterhead of the certifying firm, must list the products covered by name and Harmonized Tariff Schedule of the United States subheading number, must identify the foreign supplier by name and address, and must be signed by an authorized person;

(B) A "blanket" certification will remain valid, and may be used, for 1 year from the date of approval unless the approval is revoked earlier for cause by the port director. Separate "blanket" certifications must be approved and used for chemical substances that are subject to TSCA and for chemical substances that are not subject to TSCA; and

(C) An importer for whom the use of a "blanket" certification has been approved must include, on the invoice used in connection with the entry and entry summary procedures for each shipment covered by the "blanket" certification, a statement referring to the "blanket" certification and incorporating it by reference. This statement need not be signed.

(b) *Chemical substances or mixtures as parts of articles.* Each importer of a chemical substance or mixture as part of an article must comply with the certification requirements set forth in paragraph (a) of this section only if required to do so by a rule or order issued under TSCA.

(c) *Facsimile signatures.* The certification statements required under paragraph (a)(1) of this section may be signed by means of an authorized facsimile signature.

### 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 a new listing to the table in numerical order to read as follows:

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

19 CFR section	Description	OMB control No.
* § 12.121 .....	Approval of blanket certification under the Toxic Substances Control Act.	1515-0173

Raymond W. Kelly,  
Commissioner of Customs.

Approved: December 7, 1999.

Dennis M. O'Connell,  
Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 00-4815 Filed 2-28-00; 8:45 am]

BILLING CODE 4820-02-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 510 and 520

#### Oral Dosage Form New Animal Drugs; Change of Sponsor

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for 13 new animal drug applications (NADA's) from I. D. Russell Co., Laboratories to Alpharma Inc.

**DATES:** This rule is effective February 29, 2000.

**FOR FURTHER INFORMATION CONTACT:** Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

**SUPPLEMENTARY INFORMATION:** I. D. Russell Co., Laboratories, 1301 Iowa Ave., Longmont, CO 80501, has informed FDA that it has transferred the ownership of, and all rights and interest in, the following approved NADA's to Alpharma Inc., One Executive Dr., Fort Lee, NJ 07024: