

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 9 CFR Part 92

[Docket No. 95-053-1]

#### Horses Imported Into the United States

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to amend the horse importation regulations to clarify the information required on the application for a permit to import horses into the United States and to clarify health certificate requirements for imported horses that transit another country en route to the United States. We believe that these proposed actions are necessary to ensure that importers of horses provide adequate and accurate information on import permit applications and to ensure that horses are properly handled from the time the horses leave their farm of origin until the horses arrive in the United States. These proposed amendments appear necessary to ensure the continued protection of the health of horses in the United States.

**DATES:** Consideration will be given only to comments received on or before July 9, 1996.

**ADDRESSES:** Please send an original and three copies of your comments to Docket No. 95-053-1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 95-053-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690-2817 to facilitate entry into the comment reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. Joyce Bowling, Staff Veterinarian, Import/Export Animals, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231, (301) 734-8170.

#### SUPPLEMENTARY INFORMATION:

##### Background

The regulations in 9 CFR part 92 (referred to below as "the regulations") govern the importation into the United States of specified animals, including horses, to prevent the introduction of various animal diseases into the United States.

Under § 92.304, importers must apply for a permit to import horses into the United States. The regulations state that importers must provide certain information, including the route of travel, for horses being imported into the United States, and the required information must appear on the application for an import permit.

Under § 92.314, horses imported into the United States must be accompanied by a health certificate completed by a salaried veterinary officer of the national government of the country of origin indicating the horses' freedom from communicable diseases such as contagious equine metritis and African horse-sickness. Additionally, § 92.314 requires that "a horse presented for importation from a country where it has been for less than 60 days shall be accompanied by a like certificate similarly issued by a salaried veterinary officer of the national government of each country in which the horse has been during the 60 days immediately preceding shipment from the last country from which it is shipped to the United States."

We are proposing to amend the regulations by adding definitions of the terms "country of origin" and "country of transit" and by adding an explanation of the words "route of travel."

We propose to define "country of origin" as the "country in which the horse was born, was raised, and remained until shipment to the United States, or the country into which the horse was legally imported and has remained for a period of not less than 60 days prior to shipment to the United States." In cases of horses legally imported into their country of origin, we have determined that a 60-day residency requirement would maintain

consistency with other requirements in the regulations. We would define "country of origin" in the regulations because, in the past, there has been some confusion on the part of importers concerning the meaning of the term "country of origin," especially when a horse is moved to another country for shipment to the United States. In limited cases, the country from which the horse was directly shipped to the United States was mistakenly identified as the country of origin on the horse's import permit. We also propose to define "country of transit" as a "country through which a horse travels en route from the country of origin to the United States." A complete list of the countries of transit should appear in the "route of travel" section of the import permit application, but, on occasion, importers have mistakenly omitted countries through which a shipment of horses traveled en route to the United States.

In addition, we propose to specify that "route of travel" must include a list of all of the countries that the horse will transit en route to the United States, all of the modes of transportation that will be used to move the horse from the country of origin to the port of entry in the United States, and all of the locations where the horse will be offloaded prior to arrival at the U.S. port of entry. In the past, in addition to neglecting to list all of the countries of transit, some importers have mistakenly omitted information on the modes of transportation used to transport a shipment of horses and locations where the shipment of horses will be offloaded. Because different countries have different disease statuses, and the risk of the horses' exposure to disease increases when shipped by ground transportation and when offloaded at some locations within countries of transit, a complete assessment of the import risk associated with a particular shipment of horses is only possible when all of the essential information is available on the import permit application.

We believe that by defining the terms "country of origin" and "country of transit" and by clarifying the words "route of travel," importers would know exactly what information needs to be provided on the application for an import permit. This action would improve compliance with the regulations and continue to ensure that

horses intended for importation into the United States do not pose a disease risk to the domestic horse population.

We are also proposing to clarify the regulations concerning locations for offloading. Currently, the regulations do not specify appropriate locations where horses may be offloaded in countries of transit. We are proposing to require that if, during shipment to the United States, a horse is offloaded in a country of transit, then that horse must be offloaded in a facility that is capable of being cleaned and disinfected and that is approved by the country of transit's Ministry of Agriculture for the offloading of in-transit horses. We are also proposing to specify that while the horse is offloaded in the facility, the horse must be kept separate from all other horses. This action would reduce the risk that horses intended for importation into the United States would come into contact with other horses of unknown disease status en route to the United States.

Additionally, we are proposing to clarify the requirements concerning health certificates from countries of transit. We propose to amend § 92.314 to ensure that the regulations clearly state that if, during shipment to the United States, a horse is offloaded in a country of transit, then that horse must undergo a veterinary inspection and obtain a health certificate from a salaried veterinary officer of the national government of the country of transit in which the horse is offloaded. If a horse is offloaded in more than one country of transit, then that horse would be required to undergo a veterinary inspection and obtain a health certificate from a salaried veterinary officer of the national government in every country of transit in which the horse is offloaded. This clarification of the requirements would ensure that any communicable diseases in horses intended for importation into the United States are diagnosed as early as possible and that appropriate action is taken to prevent those diseases from being carried into the United States.

We propose that, after performing the veterinary inspection, the veterinary officer of a country of transit must complete a form that describes the horse being shipped, certifies that a health inspection has been performed on that horse, and assures that the horse is free from evidence of communicable diseases. We are proposing that the certification read, "The animals described on this form have been given a careful veterinary inspection and found to be free from evidence of communicable disease and, in my opinion, are fit to travel." The

veterinarian would sign this certificate to attest to the fact that the horse has been inspected, determined to be free of evidence of communicable diseases, and judged to be in a condition that would indicate that the animal would be in the same health upon arrival at its destination in the United States as when inspected in the country of transit. This inspection and certification would ensure that horses imported into the United States present a minimal disease risk to the U.S. horse population.

In addition, we propose to specify that the veterinary inspection must be performed in the country of transit no earlier than 24 hours before the horse is reloaded on a transport vehicle for shipment to the United States. We are proposing a 24-hour time limit in order to provide flexibility in the timing of the veterinary inspection while ensuring that the inspection takes place as close to the time of the horse's departure from a country of transit as possible.

If a horse intended for importation into the United States travels through any countries other than its country of origin and the United States but is not offloaded in a country of transit, we propose that the owner of the horse, or the owner's representative, must sign a certification statement prior to the horse's shipment from the country of origin that certifies that the horse will be shipped directly to the United States. We are proposing that the certification read, "The horse will be sent directly from the premises of origin to the premises of destination without coming into contact with other equine animals not accompanied by an official health certificate, in vehicles cleaned and disinfected in advance with a disinfectant officially recognized in the country of origin." This statement would have to be presented upon the horse's arrival in the United States. If, however, for reasons beyond the importer's or shipper's control, the horse experiences an unscheduled offloading in a country of transit, then the horse would have to undergo a veterinary inspection and obtain a health certificate from a salaried veterinary officer of the national government of the country of transit.

#### Miscellaneous

We are proposing to make other minor, nonsubstantive changes to § 92.304, such as correcting punctuation. Additionally, we are proposing to amend §§ 92.304 and 92.314 by adding a reference to the end of each section for the Office of Management and Budget control number assigned to approved

information collection and recordkeeping requirements.

#### Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We are proposing to clarify the information required on the application for a permit to import horses into the United States and to clarify health certificate requirements for imported horses that transit another country en route to the United States.

As this proposal simply clarifies the regulations and as most horses arrive in the United States with proper documentation, we do not expect a significant number of importers to be affected by this action. For importers not currently in compliance with the regulations, any cost incurred in complying with the regulations should be offset by the costs currently incurred by importers when a shipment of horses arrives in the United States without proper documentation. Currently, when a horse arrives in the United States without proper documentation, that horse remains in quarantine until the proper documents are produced, or the horse is refused entry if the proper documents are not produced. Therefore, the importer incurs additional user fee costs while the horse is held in quarantine, or the importer incurs the cost of shipping the horse back to the country of origin. Therefore, we have determined that the effect on any U.S. entities, large or small, would be insignificant.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

#### Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

#### Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information

collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 95-053-1. Please send a copy of your comments to: (1) Docket No. 95-053-1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OIRM, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would require that, upon arrival in the United States, horses travelling through countries of transit en route to the United States be accompanied by either a certification signed by the horses' owner verifying that the horses were not offloaded in any countries of transit or a certification signed by a veterinary officer of the country of transit in which the horses were offloaded that attests to the horses' freedom from evidence of communicable disease when the horse was offloaded and a veterinary inspection was performed in the country of transit. This proposed rule would therefore introduce two new information collection requirements that would enable us to ensure that horses destined for the United States are healthy when they leave their country of origin, remain healthy during their journey, and pose a minimal health risk to the U.S. horse population upon arriving in the United States. We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection. We need this outside input to help us:

- (1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;
- (2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology, e.g., permitting electronic submission of responses).

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 5 minutes per response.

*Respondents:* Veterinarians and horse owners.

*Estimated number of respondents:* 250.

*Estimated number of responses per respondent:* 1.

*Estimated Total Annual Burden on Respondents:* 21 hours.

Copies of this information collection can be obtained from the Department of Agriculture, Clearance Officer, OIRM, Ag. Box 7630, Washington, DC 20250.

#### List of Subjects in 9 CFR Part 92

Animal disease, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 92 would be amended as follows:

#### **PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON**

1. The authority citation for part 92 would continue to read as follows:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102-105, 111, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

2. Section 92.300 would be amended by adding definitions for *Country of origin* and *Country of transit*, in alphabetical order, to read as follows:

#### **§ 92.300 Definitions.**

\* \* \* \* \*

*Country of origin.* The country in which a horse was born, was raised, and remained until importation to the United States, or the country into which the horse was legally imported and remained for a period of not less than 60 days prior to shipment to the United States.

*Country of transit.* A country through which a horse travels en route from the country of origin to the United States.

\* \* \* \* \*

3. Section 92.304 would be amended as follows:

a. In paragraph (a)(1)(i), by revising the second sentence to read as set forth below.

b. At the end of the section, by adding the following: "(Approved by the Office

of Management and Budget under control number 0579-0040)".

#### **§ 92.304 Import permits for horses from countries affected with CEM, and for horse specimens for diagnostic purposes;<sup>12</sup> and reservation fees for space at quarantine facilities maintained by APHIS.**

(a) \* \* \*

(1)(i) \* \* \* The application must specify the name and address of the importer; the species, breed, number or quantity of horses or horse test specimens to be imported; the purpose of the importation; individual horse identification which includes a description of the horse, name, age, markings, if any, registration number, if any, and tattoo or ear tag; the country of origin; the name and address of the exporter; the port of embarkation in the foreign country; the route of travel from the country of origin to the United States, including the country of origin, all countries of transit, all modes of transportation, all locations, if any, where the horses will be offloaded, and the port of entry in the United States; the proposed date of arrival of the horses or horse test specimens to be imported; and the name of the person to whom the horses or horse test specimens will be delivered and the location of the place in the United States to which delivery will be made from the port of entry. \* \* \*

\* \* \* \* \*

4. Section 92.314 would be amended as follows:

a. By designating the existing text as paragraph (a) and by adding a paragraph heading to read "*General requirements.*"

b. In newly designated paragraph (a), the proviso beginning with "*And provided, further*" and the text following it is removed and new text is added in its place to read as set forth below.

c. By adding a new paragraph (b) to read as set forth below.

d. At the end of the section, by adding an OMB control number to read as set forth below.

#### **§ 92.314 Horses, certification, and accompanying equipment.**

(a) \* \* \* *And provided, further,* That upon inspecting horses at the port of entry and before permitting them to leave the port of entry, the inspector may require their disinfection and the disinfection of their accompanying equipment as a precautionary measure against the introduction of foot-and-mouth disease or any other disease dangerous to the livestock of the United States.

<sup>12</sup> See footnote 7 to subpart C.

(b) *Special requirements for horses traveling through countries of transit.* In addition to meeting all of the applicable requirements of this subpart, horses shipped to the United States through a country or countries of transit must meet the following conditions:

(1) If a horse intended for importation into the United States will travel through a country or countries of transit but will not be offloaded in the country or countries of transit, then, prior to the horse's shipment from the country of origin, the owner of the horse, or the owner's representative, must certify that the horse will be shipped directly to the United States. The certification must read as follows: "The horse will be sent directly from the premises of origin to the premises of destination without coming into contact with other equine animals not accompanied by an official health certificate, in vehicles cleaned and disinfected in advance with a disinfectant officially recognized in the country of origin." This certification must be signed by the owner of the horse or the owner's representative, and the signed certification must be presented to an inspector at the port of entry in the United States. If, after the certification is signed, an unscheduled offloading of a shipment of horses occurs in a country of transit, then the horses must meet all of the requirements of paragraphs (b)(2) and (b)(3) of this section.

(2) If a horse intended for importation into the United States will travel through a country or countries of transit and will be offloaded in the country or countries of transit, then the horse must be offloaded in a facility that is capable of being cleaned and disinfected and that is approved by the country of transit's Ministry of Agriculture for the offloading of in-transit horses. Within the facility, the horse must be kept separate from all other horses. All horses offloaded in a country or countries of transit must undergo a veterinary inspection and receive a health certificate from a salaried veterinary officer of the national government of each country of transit in which the horse is offloaded. The veterinary inspection must be performed no earlier than 24 hours before the horse is reloaded on a transport vehicle for shipment. If, after performing the inspection, the salaried veterinary officer of the national government of the country of transit finds the horse intended for importation into the United States to be free of evidence of communicable diseases and fit to travel, the veterinary officer must complete the form shown in paragraph (b)(3) of this section.

(3) A completed certificate of inspection, as shown below, must accompany any horse offloaded in a country of transit to the U.S. port of arrival and be produced for the inspector at the port of arrival upon the horse's arrival in the United States.

#### Certification of Inspection of Import Animals

1. Permit No. \_\_\_\_\_
2. Consignor's Name (Last name, first name, middle initial or business name) \_\_\_\_\_
3. Consignor's Street Address (Mailing address) \_\_\_\_\_
4. Consignor's City/Town \_\_\_\_\_
5. Consignor's Country \_\_\_\_\_
6. Consignee's Name (Last name, first name, middle initial or business name) \_\_\_\_\_
7. Consignee's City/Town \_\_\_\_\_
8. Consignee's State \_\_\_\_\_
9. Species of Animals Certified for Import \_\_\_\_\_
10. Country of Origin \_\_\_\_\_
11. Breed of Animals Certified for Import \_\_\_\_\_
12. Number of Animals Inspected \_\_\_\_\_
13. Country of Transit/City in Which Inspection Occurred \_\_\_\_\_
14. Date of Arrival in and Date of Departure from Country of Transit \_\_\_\_\_
15. Name of Veterinarian Performing Inspection in Country of Transit \_\_\_\_\_
16. Signature of Veterinarian Performing Inspection in Country of Transit \_\_\_\_\_
17. Date Issued \_\_\_\_\_
18. Seal \_\_\_\_\_
19. Remarks \_\_\_\_\_

The animals described on this form have been given a careful veterinary inspection and found to be free from evidence of communicable disease and, in my opinion, fit to travel.

16. Signature of Veterinarian Performing Inspection in Country of Transit \_\_\_\_\_

17. Date Issued \_\_\_\_\_

18. Seal \_\_\_\_\_

19. Remarks \_\_\_\_\_

(Approved by the Office of Management and Budget under control number 0579-0040)

Done in Washington, DC, this 3rd day of May 1996.

Terry L. Medley,

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 96-11635 Filed 5-9-96; 8:45 am]

BILLING CODE 3410-34-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Chapter 1

[Docket No. 96N-0094]

#### Uniform Compliance Date for Food Labeling Regulations; Correction

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

**ACTION:** Proposed rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the Federal Register of April 15, 1996 (61 FR 16422). The document proposed to establish January 1, 1998, as its new

uniform compliance date for all food labeling regulations that are issued after the publication of a final rule based on the proposal and before January 1, 1997. The document was published with an editorial error. This document corrects that error.

#### FOR FURTHER INFORMATION CONTACT:

Gerard L. McCowin, Center for Food Safety and Applied Nutrition (HFS-150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4561.

In FR Doc. 96-9319, appearing on page 16422 in the Federal Register of Monday, April 15, 1996, the following correction is made:

1. On page 16422, in the first column, after the "DATES" caption, a new caption is added to read as follows: "ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857."

Dated: May 6, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96-11788 Filed 5-9-96; 8:45 am]

BILLING CODE 4160-01-F

## 21 CFR Part 328

[Docket No. 95N-0341]

### Over-the-Counter Drug Products Intended for Oral Ingestion that Contain Alcohol; Proposed Amendment of Final Rule

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend the regulations for over-the-counter (OTC) drug products intended for oral ingestion that contain alcohol as an inactive ingredient by exempting ipecac syrup from the maximum concentration limits of 0.5 percent alcohol or less when used by children under 6 years of age. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

**DATES:** Submit written comments by June 10, 1996; written comments on the agency's economic impact determination by June 10, 1996. The agency is proposing that any final rule based on this proposal become effective on the date of its publication in the Federal Register.

**ADDRESSES:** Submit written comments to the Dockets Management Branch