

# 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 3

[Docket No. 93-076-14]

#### Animal Welfare; Marine Mammals

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

**ACTION:** Notice of reopening and extension of comment period.

**SUMMARY:** We are reopening and extending the comment period for our proposed rule to amend the Animal Welfare Act regulations concerning the humane handling, care, treatment, and transportation of marine mammals in captivity. This action will allow interested persons additional time to prepare and submit comments.

**DATES:** We invite you to comment on Docket No. 93-076-11. We will consider all comments that we receive by May 26, 1999.

**ADDRESSES:** Please send your comment and three copies to: Docket No. 93-076-11, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Please state that your comment refers to Docket No. 93-076-11.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webpor.html>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Barbara Kohn, Senior Staff Veterinarian, Animal Care, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737-1228, (301) 734-7833.

#### SUPPLEMENTARY INFORMATION:

##### Background

On February 23, 1999, we published in the **Federal Register** (64 FR 8735-8755, Docket No. 93-076-11) a proposal to amend the Animal Welfare Act regulations concerning the humane handling, care, treatment, and transportation of marine mammals in captivity. The proposed regulations were developed by the Marine Mammal Negotiated Rulemaking Advisory Committee.

Comments on the proposed rule were required to be received on or before April 26, 1999. We are reopening and extending the comment period on Docket No. 93-076-11 for 30 days to May 26, 1999. This action will allow interested persons additional time to prepare and submit comments.

**Authority:** 7 U.S.C. 2131-2159; 7 CFR 2.22, 2.80, and 371.2(d).

Done in Washington, DC, this 10th day of April 1999.

**Joan M. Arnoldi,**

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

[FR Doc. 99-12236 Filed 5-13-99; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 207, 607, and 807

[Docket No. 98N-1215]

#### Foreign Establishment Registration and Listing

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations pertaining to the registration of foreign establishments and the listing of human drugs, animal drugs, biological products, and devices. The proposal would require foreign establishments whose products are imported or offered for import into the

United States to register with FDA. The proposal would also require foreign establishments to identify a United States agent and would describe some of the agent's responsibilities. The agency is proposing these changes to implement section 417 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) as it pertains to foreign establishment registration.

**DATES:** Written comments by July 28, 1999. Written comments on the information collection requirements by June 14, 1999.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20502, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Philip L. Chao, Office of Policy (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

On November 21, 1997, the President signed FDAMA into law (Pub. L. 105-115). Section 417 of FDAMA amended section 510(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)) to require, in part, that:

(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

(2) The establishment shall also provide the information required by subsection (j).

\* \* \*

(Section 510(j) of the act pertains to product listing.)

Generally speaking, before FDAMA's enactment, foreign establishments could, but were not required to, register with FDA. Foreign establishments were required, however, to list their products regardless of whether the foreign establishment was registered (see, e.g.,