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List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

42 CFR Part 71

Airports, Animals, Communicable diseases, Harbors, Imports, Pesticides and pests, Public health, Quarantine, Reporting and recordkeeping requirements.

■ Therefore, under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs and to the Director, Centers for Disease Control and Prevention, 21 CFR parts 16 and 1240 and 42 CFR part 71 are amended as follows:

21 CFR CHAPTER I

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for 21 CFR Part 16 continues to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

■ 2. Section 16.1 is amended in paragraph (b)(2) by numerically adding an entry for § 1240.63(c)(3) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 1240.63(c)(3), relating to a written order to cause an animal to be placed in quarantine or to cause an animal to be destroyed.

* * * * *

PART 1240—CONTROL OF COMMUNICABLE DISEASES

■ 3. The authority citation for 21 CFR part 1240 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 264, 271.

■ 4. Section 1240.63 is added to subpart D to read as follows:

§ 1240.63 African rodents and other animals that may carry the monkeypox virus.

(a) *What Actions Are Prohibited? What Animals Are Affected?*

(1) Except as provided in paragraph (a)(2) of this section,

(i) You must not capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, or release into the environment, any of the following animals, whether dead or alive:

(A) Prairie dogs (*Cynomys* sp.),

(B) African Tree squirrels

(*Heliosciurus* sp.),

(C) Rope squirrels (*Funisciurus* sp.),

(D) African Dormice (*Graphiurus* sp.),

(E) Gambian giant pouched rats

(*Cricetomys* sp.),

(F) Brush-tailed porcupines

(*Atherurus* sp.),

(G) Striped mice (*Hybomys* sp.), or

(H) Any other animal so prohibited by order of the Commissioner of Food and Drugs because of that animal's potential to transmit the monkeypox virus; and

(ii) You must not prevent, or attempt to prevent, the Food and Drug Administration (FDA) from causing an animal to be quarantined or destroyed under a written order for the animal's quarantine or destruction.

(2) The prohibitions in paragraph (a)(1) of this section do not apply if you:

(i) Transport an animal listed in paragraph (a)(1) of this section, or covered by an order by the Commissioner of Food and Drugs, to veterinarians or animal control officials for veterinary care, quarantine, or destruction purposes; or

(ii) Have written permission from FDA to capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, and/or release into the environment an animal listed in paragraph (a)(1) of this section, or covered by an order by the Commissioner of Food and Drugs. You may not seek written permission to sell, barter, or exchange, or offer to sell, barter, or exchange, as a pet, an animal listed in paragraph (a)(1) of this section or covered by an order by the Commissioner of Food and Drugs.

(A) To obtain such written permission from FDA, you must send a written request to the Division of Compliance (HFV-230), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, Attn: Listed Animal Permit Official. You may also fax your request to the Division of Compliance (using the same address in the previous sentence) at 301-827-1498.

(B) Your request must state the reasons why you need an exemption, describe the animals involved, describe the number of animals involved, describe how the animals will be transported (including carrying containers or cages, precautions for handlers, types of vehicles used, and other procedures to minimize exposure of animals and precautions to prevent animals from escaping into the environment), describe any holding facilities, quarantine procedures, and/or veterinarian evaluation involved in the animals' movement, and explain why an