

## **§ 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 exemption will not result in the spread of monkeypox within the United States.

(C) We (FDA) will respond, in writing, to all requests, and we also may impose conditions in granting an exemption.

(b) *What Actions Can FDA Take?* (1) To prevent the monkeypox virus from spreading and becoming established in the United States, we may, in addition to any other authorities under this part:

(i) Issue an order causing an animal to be placed in quarantine,

(ii) Issue an order causing an animal to be destroyed, or

(iii) Take any other action necessary to prevent the spread of the monkeypox virus.

(2) Any order to cause an animal to be placed in quarantine or to cause an animal to be destroyed will be in writing.

(c) *How Do I Appeal an Order?* (1) If you receive a written order to cause an animal to be placed in quarantine or to cause an animal to be destroyed, you may appeal that order. Your appeal must be in writing and be submitted to the Food and Drug Administration District Director whose office issued the order, and you must submit the appeal within two business days after you receive the order.

(2) As part of your appeal, you may request an informal hearing. Your appeal must include specific facts showing there is a genuine and substantial issue of fact that requires a hearing.

(3) If we grant your request for an informal hearing, we will follow the regulatory hearing requirements at in part 16, except that:

(i) The written order will serve as notice of opportunity for that hearing, for purposes of §16.22(a) of this chapter;

(ii) The presiding officer will issue a decision rather than a report and a recommended decision. The presiding officer's decision constitutes final agency action.

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