

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.

**42 CFR CHAPTER I**

**PART 71—FOREIGN QUARANTINE**

■ 5. The authority citation for 42 CFR part 71 continues to read as follows:

**Authority:** Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243), secs. 361–369, PHS Act, as amended (42 U.S.C. 264–272).

■ 6. Section 71.56 is added to subpart F read as follows:

**§ 71.56 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 paragraphs (a)(2) and (a)(3) of this section,

(i) You must not import or attempt to import any rodents, whether dead or alive, that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, any products derived from such rodents, any other animal, whether dead or alive, whose importation the Director has prohibited by order, or any products derived from such animals; and

(ii) You must not prevent or attempt to prevent the Centers for Disease Control and Prevention (CDC) from causing an animal to be quarantined, re-exported, or destroyed under a written order.

(2) The prohibitions in paragraph (a)(1) of this section do not apply if you have written permission from CDC to import a rodent that was obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or an animal whose importation the Director has prohibited by order.

(i) To obtain such written permission from CDC, you must send a written request to Division of Global Migration and Quarantine, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30333. You may also fax your request to the Division of Global Migration and Quarantine (using the same address in the previous sentence) at 404–498–1633.

(ii) 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. Your request must be limited to scientific, exhibition, or educational purposes.

(iii) We will respond in writing to all requests, and we also may impose conditions in granting an exemption. If we deny your request, you may appeal that denial. Your appeal must be in writing and be submitted to the CDC official whose office denied your request, and you must submit the appeal within two business days after you receive the denial. Your appeal must state the reasons for the appeal and show that there is a genuine and

substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

(3) The prohibitions in paragraph (a) of this section do not apply to products derived from rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or products derived from any other animal whose importation the Director has prohibited by order if such products have been properly processed to render them noninfectious so that they pose no risk of transmitting or carrying the monkeypox virus. Such products include, but are not limited to, fully taxidermied animals and completely finished trophies; and they may be imported without written permission from CDC.

**(b) What Actions Can CDC 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 re-exported,

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

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

(2) Any order causing an animal to be quarantined, re-exported, or destroyed will be in writing.

**(c) How Do I Appeal an Order?** If you received a written order to quarantine or re-export an animal or to cause an animal to be destroyed, you may appeal that order. Your appeal must be in writing and be submitted to the CDC official whose office issued the order, and you must submit the appeal within 2 business days after you receive the order. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

Dated: October 6, 2003.

**Tommy G. Thompson,**

*Secretary of Health and Human Services.*

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