

importation, sale, distribution, release, disposal, and/or display of prairie dogs and certain rodents (Refs. 5 through 11). However, these State efforts are limited to their respective jurisdictions, and some State orders or rules expire on a specific date, while others differ in the types of animals and actions that are covered. Communicable diseases, such as monkeypox, are not confined by State borders and, as shown by the presence of the monkeypox virus in prairie dogs, may affect multiple animal species. Consequently, Federal action was necessary to help prevent the spread of monkeypox. On June 11, 2003, the Director of CDC and the Commissioner of Food and Drugs, under 42 CFR 70.2 and 21 CFR 1240.30 respectively, issued a joint order (Ref. 12) prohibiting, until further notice, the transportation or offering for transportation in interstate commerce, or the sale, offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of:

- Prairie dogs (*Cynomys* sp.);
- Tree squirrels (*Heliosciurus* sp.);
- Rope squirrels (*Funisciurus* sp.);
- Dormice (*Graphiurus* sp.);
- Gambian giant pouched rats (*Cricetomys* sp.);
- Brush-tailed porcupines (*Atherurus* sp.), and
- Striped mice (*Hybomys* sp.).

The June 11, 2003, order did not apply to the transport of these animals to veterinarians or animal control officials or other entities under guidance or instructions issued by Federal, State, or local government authorities. In addition, under 42 CFR 71.32(b), CDC implemented an immediate embargo on the importation of all rodents from Africa (order *Rodentia*).

Both CDC and FDA are also working closely with other Federal agencies, such as the Animal and Plant Health Inspection Service (APHIS) in the Department of Agriculture (USDA), the Fish and Wildlife Service (FWS) in the Department of the Interior, Customs and Border Protection in Department of Homeland Security, and the Department of Transportation. FDA and CDC are also working with numerous State and local agencies to prevent further exposure of animals and people to the monkeypox virus.

III. What Does The Interim Final Rule Do?

A. Why Are FDA and CDC Issuing an Interim Final Rule?

We issued the June 11, 2003, order to address quickly what was then a new and rapidly developing monkeypox

outbreak (Ref. 13). We now are able to provide a more detailed set of measures aimed at creating a regulatory approach to prevent the monkeypox virus from becoming established and spreading in the United States, with exemption procedures to accommodate special circumstances, and are doing so by issuing this interim final rule. This interim final rule supersedes the June 11, 2003, order. As appropriate, we will amend the interim final rule in response to comments and to any new developments in the monkeypox outbreak.

This interim final rule creates two complementary regulations. First, with respect to certain animals that are in the United States, the interim final rule adds 21 CFR 1240.63, entitled “African rodents and other animals that may carry the monkeypox virus.” FDA will enforce 21 CFR 1240.63. Second, for African rodents that are being imported or offered for import to the United States, the interim final rule adds 42 CFR 71.56, that is also entitled “African rodents and other animals that may carry the monkeypox virus.” CDC will enforce 42 CFR 71.56. Together, 21 CFR 1240.63 and 42 CFR 71.56 are intended to prevent the establishment and spread of the monkeypox virus in the United States.

Section 361 of the Public Health Service Act (PHS act) (42 U.S.C. 264) serves as the legal authority for both 21 CFR 1240.63 and 42 CFR 71.56. Section 361 of the PHS act gives the Secretary of Health and Human Services the authority to make and enforce regulations to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the States or from one State to another State. As we explain in section IV of this document, both FDA and CDC have issued regulations under section 361 of the PHS act, and several FDA regulations are similar or identical to CDC regulations. Here, however, the responsibilities are being divided between our two agencies. FDA’s regulation focuses on animals moving between and within States while CDC’s regulation focuses on imported animals. Our goal in creating separate FDA and CDC regulations is to use our limited resources to deal with the current monkeypox situation in the most efficient manner possible.

B. What Does FDA’s Rule Say?

1. Where Is the Rule Codified? (21 CFR 1240.63)

As we stated in section III.A of this document, the interim final rule adds 21 CFR 1240.63, entitled “African rodents

and other animals that may carry the monkeypox virus.”

2. What Does the Rule Prohibit? (21 CFR 1240.63(a))

21 CFR 1240.63(a)(1) contains several general prohibitions. In brief, under 21 CFR 1240.63(a)(1)(i), regardless of your status (such as a pet dealer, pet owner, researcher, animal trapper, zoological park administrator, etc.), 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:

- Prairie dogs (*Cynomys* sp.),
- African Tree squirrels (*Heliosciurus* sp.),
- Rope squirrels (*Funisciurus* sp.),
- African Dormice (*Graphiurus* sp.),
- Gambian giant pouched rats (*Cricetomys* sp.),
- Brush-tailed porcupines (*Atherurus* sp.),
- Striped mice (*Hybomys* sp.), or
- 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.

For convenience, this preamble will refer to the above animals as “listed animals.”

The interim final rule covers the listed animals because animals from those species have been associated, either directly through laboratory tests or indirectly through epidemiological evidence, in the current outbreak of the monkeypox virus in humans (Ref. 14). In general, the animals identified in 21 CFR 1240.63 are the same as those listed in the CDC-FDA order dated June 11, 2003, except that the rule also refers to other, yet-unspecified kinds of animals that the Commissioner of Food and Drugs may prohibit by order. FDA included the latter “catch-all” provision in § 1240.63 because the agency cannot preclude the possibility that monkeypox may spread to other animal species, and, if monkeypox is found in other animals, FDA needs to be able to list those animals quickly. FDA derives its authority to list such animals by order from section 361 of the Public Health Service Act, which is the same statutory authority under which it is issuing this interim final rule. This statutory provision authorizes the Secretary to make and enforce regulations to prevent the introduction, transmission, and spread of communicable diseases. Section 1240.63(b)(1) of the interim final rule (which we discuss later in this section) allows FDA to issue orders causing such animals to be quarantined or destroyed and to “take any other action necessary to prevent the spread