

of the monkeypox virus.” Such “other actions” may include issuing orders necessary to prevent the spread of monkeypox. An order adding animals to those “listed animals” that have the potential to transmit the monkeypox virus is such an order since control of animals that may transmit monkeypox is necessary to prevent the spread of this communicable disease.

The interim final rule prohibits capture, offers to capture, transport, offers to transport, sale, barter, or exchange, offers to sell, barter, or exchange distribution, offers to distribute, or release of a listed animal into the environment regardless of whether the activity is interstate or intrastate. The June 11, 2003, order referred to “transportation in interstate commerce.” This created some confusion about whether the order applied to activities occurring within a State. In this interim final rule, FDA makes clear that the restrictions apply to both interstate and intrastate activities. The interim final rule must reach intrastate activities because FDA cannot effectively prevent interstate transmission of communicable disease without addressing intrastate transmission. This is due to the fact that an infected animal could transmit the monkeypox virus to other animals within a State, and eventually and inevitably the monkeypox virus would be transmitted to other States as infected wild animals or even infected, domesticated animals crossed State borders. Effective intrastate controls are, therefore, an integral part of efforts to prevent interstate transmission of communicable disease.

21 CFR 1240.63(a)(1)(i) also prohibits the capture and offers to capture listed animals. For purposes of this rule, “capture” means the act of catching or confining an animal in the wild with the intent of removing that animal for sale, barter, or exchange, distribution, and/or release into the environment. So, for example, 21 CFR 1240.63(a)(1)(i) prohibits a person from taking prairie dogs from their burrows for purposes of selling those prairie dogs, but it would not consider the act of immobilizing a prairie dog, taking measurements or biological samples (such as blood samples), and then releasing the prairie dog as constituting “capture.” Similarly, if a prairie dog escaped from its cage in a pet store, catching the prairie dog to put it back in its cage would not constitute “capture” within 21 CFR 1240.63(a)(1)(i). As another example, individuals sometimes shoot prairie dogs because their burrows may present a hazard to cattle and horses; shooting a prairie dog would not constitute

“capture” within 21 CFR 1240.63(a)(1)(i). We recommend that you dispose of dead prairie dogs appropriately in consultation with State wildlife control officials and following applicable CDC guidance. The prohibition against capture and offers to capture is an appropriate and logical extension of the June 11, 2003, order because, for example, it would be illogical to prohibit wild prairie dogs from being transported, but still allow them to be captured. An infectious animal could transmit the monkeypox virus to humans during its capture, just as it could transmit the monkeypox virus when a human handled the animal during transport. Therefore, the interim final rule prohibits the capture of listed animals and offers to capture such animals.

Furthermore, 21 CFR 1240.63(a)(1)(i) prohibits the distribution of listed animals. Prohibiting distribution is another appropriate and logical extension of the June 11, 2003, order. The June 11, 2003, order prohibited, in relevant part, “offering for commercial or public distribution,” yet was silent regarding the actual distribution of listed animals. To clarify FDA’s intent, 21 CFR 1240.63(a)(1)(i) prohibits the distribution of listed animals in addition to the other prohibitions. FDA has also simplified the rule by prohibiting offers to distribute listed animals rather than “offers for commercial or public distribution” that were in the June 11, 2003, order. The June 11, 2003, order made no distinction between “commercial or public distribution” and other types of distribution, nor did it indicate that non-commercial or nonpublic distribution presented lesser risk of transmitting the monkeypox virus. Consequently, 21 CFR 1240.63(a)(1)(i) now states, in relevant part, that you must not “offer to distribute” a listed animal.

21 CFR 1240.63(a)(1)(i) also prohibits “sale, barter, or exchange” and “offers to sell, barter, or exchange” listed animals. Animals are sometimes traded or exchanged at “swap meets,” and such trades or exchanges might not be considered to be “sales.” Therefore, 21 CFR 1240.63(a)(1)(i) prohibits the sale, barter, or exchange of listed animals and offers to sell, barter, or exchange listed animals.

FDA wishes to clarify that 21 CFR 1240.63 applies regardless of whether an animal is alive or dead. Dead animals could still harbor the monkeypox virus and could be infectious, so the agency cannot ignore such dead animals as a potential source for infection. Therefore, to protect the public health to the best

extent possible, 21 CFR 1240.63(a)(1)(i) pertains to dead animals.

21 CFR 1240.63(a)(1)(ii) states that you must not prevent or attempt to prevent FDA from causing a listed animal to be quarantined or destroyed pursuant to a written order for the animal’s quarantine or destruction. (For purposes of this rule, “quarantine” means that the animal is held or stored in an isolated area, and all further movement has been restricted so as not to expose other animals.) Although most individuals will cooperate with a written order to destroy an infected animal, some individuals may want to avoid causing an animal’s destruction by releasing the animal instead (Ref. 15). Releasing an infected or potentially infected animal would create a serious risk to animal and human health because the monkeypox virus could then spread to domestic animal species and to humans and could become established in the United States. Therefore, if you prevent or attempt to prevent FDA from causing an animal to be quarantined or destroyed, you may be subject to criminal penalties. Penalties are discussed in part IV below.

FDA repeats that prohibiting the capture, offer to capture, transport, offer to transport, sale, barter, or exchange, offer to sell, barter, or exchange, distribution, offer to distribute, and release of listed animals is vital to prevent the monkeypox virus from becoming established and spreading in the United States. Nevertheless, the agency also recognizes that there are limited circumstances warranting exemptions from some prohibitions, such as the need to transport an animal for zoological, educational, medical, scientific, or other purposes. Consequently, 21 CFR 1240.63(a)(2) allows you to:

- Transport a listed animal to a veterinarian or animal control official for veterinary care, quarantine, or destruction purposes; and

- 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 a listed animal into the environment after receiving written permission from FDA. Section 1240.63(a)(2)(ii) states, however, that you may not seek written permission to sell, barter, exchange, or offer to sell, barter, or exchange a listed animal as a pet. We do not intend to permit pet sales (or barter or exchange) because the monkeypox outbreak developed in the pet industry, and exposure to infected animals intended as pets led to infections in prairie dogs. The infected prairie dogs, in turn, infected humans.