

Thus, compared to animals in the wild pets present a greater potential risk for transmitting the monkeypox virus.

To illustrate when transport of a listed animal to a veterinarian or animal control official would be allowed, assume that an individual has a prairie dog that appears to be ill. Section 1240.63(a)(1)(i) would prohibit transportation of that animal, yet, under 21 CFR 1240.63(a)(2)(i), an individual could transport the prairie dog to a veterinarian for treatment. As another example, individuals might shoot prairie dogs because their burrows present a hazard to cattle and horses. In such a situation, 21 CFR 1240.63(a)(1)(i) would prohibit transportation of the prairie dog carcasses. However, under 21 CFR 1240.63(a)(2)(i), an individual could transport the prairie dog carcasses to animal control officials for incineration or other appropriate means of disposal.

21 CFR 1240.63(a)(2)(ii)(A) describes the procedures for seeking written permission from FDA. 21 CFR 1240.63(a)(2)(ii)(B) requires you to 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. For example, the description of the animals involved should identify the animal(s) and discuss the number of animals involved, their environment, and health conditions. The explanation of your reasons for seeking an exemption should show the justification, including need and benefits, relating to the requested exemption (such as public health reasons, scientific research, ecological reasons, etc.). FDA will grant exemptions on a case-by-case basis and only for specific purposes and in specific circumstances. Thus, for example, if you receive written permission to transport prairie dogs from city A to city B, but you later want to move the same prairie dogs to a third location, city C, you would have to seek written permission to move the prairie dogs from city B to city C. Depending on the number and nature of exemption requests it receives, FDA may publish a

guidance document to describe the types of information it would like to see in an exemption request. Under 21 CFR 1240.63(a)(2)(ii)(C), FDA will respond, in writing, to all requests, and it also may impose conditions in granting an exemption. If FDA decides against granting written permission, that decision could be reviewed under 21 CFR 10.75 ("Internal agency review of decisions").

To illustrate when a person might seek written permission from FDA, the agency notes that efforts to reintroduce black-footed ferrets into certain areas may depend on the ability to transport wild prairie dogs and release them into the environment (Ref. 16). The black-footed ferrets use prairie dog burrows for shelter and also feed on prairie dogs. Thus, in this example, biologists working to reintroduce black-footed ferrets would seek written permission from FDA to capture, transport, and release prairie dogs in connection with each black-footed ferret program. They would also remain subject to any other Federal, State, local or tribal requirements.

In the previous example, the efforts involving the black-footed ferrets may have been the subject of other Federal and State permits. We acknowledge that the June 11, 2003, order stated that its prohibitions did not apply to persons who transport listed animals to veterinarians or animal control officials "or other entities pursuant to guidance or instructions issued by federal, State, or local government authorities." The order's reference to Federal, State, and local government authorities has created some confusion as to whether any Federal or State permit issued before June 11, 2003, constituted "guidance or instructions" that would create an exception to the order. Through this interim final rule, we are clarifying that we do not consider all Federal, State, or local government permits as automatically creating an exception to the prohibitions against transport, sale, etc., because we have no assurance that such Federal, State, or local government permits provide adequate safeguards to prevent the spread of the monkeypox virus. Therefore, 21 CFR 1240.63(a)(2)(ii) requires you to obtain 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 a listed animal into the environment.

We also acknowledge that 21 CFR 1240.63(a)(2)(ii) appears to conflict with a position that we took on July 2, 2003, in a document titled, "Wild-to-Wild

Translocation or Transportation of Prairie Dogs" ("Wild-to-Wild document") (Ref. 17). The Wild-to-Wild document was intended to address situations where a wild population of prairie dogs would be relocated to another wild habitat, and the document suggested that States that have not been implicated in the monkeypox outbreak issue guidance or instructions for translocating prairie dogs within a State, and it listed the States that had been implicated in the monkeypox outbreak as of June 27, 2003. The Wild-to-Wild document was interpreted as giving State and local governments in nonimplicated States the ability to decide on translocating prairie dogs without having to obtain an exemption from FDA or CDC. However, the policies expressed in the Wild-to-Wild document have caused some uncertainty, particularly as some States have been listed as being affected by the monkeypox virus, and then "de-listed." For example, if a person began translocating prairie dogs in a non-listed State, but the State was then listed before the translocation process could be completed, should that person seek an exemption from FDA for those prairie dogs that had not been translocated before the State was listed? Or could the person complete the translocation process without an exemption from FDA because the translocation process began when the State was not listed? The Wild-to-Wild document also created the potential for conflicting policies between States. For example, one State could adopt strict criteria to ensure that certain safeguards were observed, while a neighboring State could have no criteria at all and decide on wild-to-wild translocations on an ad hoc basis. Given these issues and potential problems, we have decided that the written permits in 21 CFR 1240.63(a)(2)(ii)(B) must be obtained and will no longer observe the policies expressed in the Wild-to-Wild document. In other words, all wild-to-wild translocations or transportation of prairie dogs, other than those that occurred before the date of this interim final rule, will need a written permit under 21 CFR 1240.63(a)(2)(ii)(B), and the interim final rule supersedes the Wild-to-Wild document.

3. What Actions Can FDA Take? (21 CFR 1240.63(b))

FDA has limited knowledge as to which kinds of animals in the United States may be vulnerable to the monkeypox virus, but it is extremely difficult, if not impossible, to eradicate a virus once it becomes established in a country or region. For example, the