

unless we determine that the ban was necessary to protect health and safety. The economic advantage of this alternative relative to this interim final rule may be the elimination of permitting costs for transport in domestic animals in the case that monkeypox has not become endemic. It may, again, provide for later capture, transport, sale, barter, exchange, distribution, or release of an animal that may carry other diseases. This alternative was not accepted because of the uncertainty in predicting when a ban would no longer be necessary.

A second alternative would have been to allow the continued capture, transport, sale, barter, exchange, distribution, or release of the listed animals, effectively doing nothing to reduce the risk of further spread of monkeypox. Although the market for at least prairie dogs was apparently greatly reduced due to public knowledge of the monkeypox issue and seasonal variation in the prairie dog market, this option would have allowed those few in the market that dismissed the severity of the problem to continue to pose a risk that monkeypox would become endemic to domestic pets and wildlife and further affect human health. For this reason it was determined to be not acceptable.

A third alternative would have been to exempt small businesses from this interim final rule. However, because about 94 percent of pet stores and probably a large portion of small animal trappers and wholesalers/distributors are small businesses, this option would have compromised the rule's ability to reduce the risk of establishing or spreading the monkeypox virus in the United States.

VII. Paperwork Reduction Act of 1995

This interim final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C.

3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Both FDA and CDC have requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). Such emergency processing is necessary in order to respond immediately to the monkeypox outbreak. This interim final rule, at 21 CFR 1240.63(a)(2)(ii)(A) and (B) and 42 CFR 71.56(a)(2)(i) and (ii), contains information collection requirements. In compliance with the PRA (44 U.S.C. 3507(d)), we have submitted a copy of the information collection provisions of this interim final rule to OMB for review.

The information collections in this interim final rule have been approved under OMB control number 0910–0519 (for 21 CFR 1240.63) and OMB control number 0920–0615 (for 42 CFR 71.56). An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it contains a currently valid OMB control number.

Title: Control of Communicable Diseases; Requests for Exemptions from the Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals.

Description: Monkeypox is a rare zoonotic viral disease that occurs primarily in the rain forest countries of central and west Africa. Studies have shown that infected rodents are capable of transmitting the monkeypox virus to humans. Limited person-to-person spread of infection has been reported in disease-endemic areas in Africa. It is likely the virus is entering the United States by way of rodent species

imported from Africa. Further transmission of the virus likely occurred in the storage and handling of these rodents during sale and distribution within the United States. This resulted in secondary transmission to domestic prairie dogs in this country housed in the same animal-holding facility or pet shop. Introduction of exotic species, such as African rodents, poses a serious public health threat because of the potential of human monkeypox virus infection. Transport, sale, or any other type of distribution, including release into the environment, of certain species of rodents poses a serious public health threat because of the potential for further spread of the monkeypox virus to other animal species and to humans. To prevent the establishment and spread of the monkeypox virus in the United States, we are prohibiting the capture, offer to capture, transport, offer to transport, sale, barter, or exchange, offer to sell, barter, or exchange, distribution, offer to distribute, or release into the environment of prairie dogs and certain rodents and any other animal so prohibited by order of the Commissioner of Food and Drugs. We are also prohibiting the importation of all rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or any other animal whose importation the Director of CDC has prohibited by order. The rule provides for exemptions from these prohibitions and discusses our authority to issue orders causing an animal to be quarantined, re-exported, or destroyed. The information collection burden is associated with the process for seeking an exemption.

Description of Respondents: Persons who capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, import, offer to import, or release into the environment certain rodents.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

CFR Section	No. of Respondents	Annual Frequency per Response	Total No. of Responses	Hours per Response	Total Hours
21 CFR 1240.63(a)(2)(ii)(A) and (B)	60	1	60	2	120
42 CFR 71.56(a)(2)(i) and (ii)	12	1	12	0.5–1.0	10
				Total	130

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on our experience to date with the June 11, 2003, order and on similar requests under FDA regulations. To estimate the

number of respondents, we examined the number of requests and inquiries we have received since the June 11, 2003, order. Both FDA and CDC have received

fewer than 10 requests, and most requests involved requests to move an animal from one location to another. (FDA also has received many inquiries.)