

As we cannot predict how the monkeypox outbreak will be resolved, we will tentatively estimate that there will be 60 respondents for FDA's provisions and 10 respondents for CDC's provisions. Furthermore, based on FDA's experience with submissions seeking exemptions or waivers, we will tentatively estimate that each respondent will need 2 hours to complete its request for an exemption. Therefore, the total reporting burden under 21 CFR 1240.63(a)(2)(ii)(A) and (B) will be 120 hours (60 respondents x 2 hours per response = 120 hours).

CDC's estimates for the burden of its data collection are based on its experience with the importation of non-human primates. CDC estimates that there will be 12 respondents annually for this data collection. Respondents will include individuals, businesses, and organizations. Although CDC estimates that most respondents will submit only one request per year, CDC feels that organizations may submit 2 requests per year. Individuals and businesses submitting requests will need 30 minutes to prepare the request. Organizations will need 1 hour to prepare an initial request and 10 minutes for subsequent requests. The total annualized burden under 42 CFR 71.56(a)(2)(i) and (ii) will be 10 hours.

The requirements contained in 21 CFR 1240.63(c) and 42 CFR 71.56(c) are not subject to review by OMB because they are exempted under 5 CFR § 1320(a)(4), which exempts "administrative actions \* \* \* involving an agency against specific individuals or entities."

## VIII. Federalism

We have analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132 and have determined that the rule has federalism implications. Federal restrictions on the capture, offering to capture, transport, offering to transport, sale, barter, or exchange, or offering to sell, barter, or exchange, distribution, offering to distribute, or release into the environment of certain rodents and prairie dogs are both necessary and appropriate to prevent the establishment and spread of monkeypox virus in the United States. In accordance with section 361(e) of the PHS act (42 U.S.C. 264(e)), nothing in this interim final rule supersedes any provisions of State or local law except to the extent that such a provision conflicts with this interim final rule. For example, the interim final rule does not prevent a State from taking stronger measures to deal with infected or possibly infected animals or to cover additional species. Furthermore, while

some States have issued orders with restrictions that cover fewer animal species, those State requirements do not conflict with the interim final rule and would also not be superseded. However, in accordance with section 361(e) of the PHS act, any State or local law that would permit any activity prohibited under this interim final rule would be in conflict with this rule and, therefore, would be superseded.

We note that we have been in direct contact with many States regarding the June 11, 2003, order and efforts to prevent the spread of monkeypox. We believe that the public health requires us to give this regulation immediate effect. Through this interim final rule, and under to section 4(e) of Executive Order 13132, we are providing all affected State, local, and tribal officials notice and opportunity to participate in this rulemaking.

## IX. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## X. References

The following references have been placed on display in the Division of Dockets Management and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Khodakevich, L., Jezek, Z. and Messenger, D., "Monkeypox Virus: Ecology and Public Health Significance," *Bulletin of the World Health Organization*, 66: 747-752, 1988. This reference identifies several species of squirrels as playing a major role as a reservoir for the monkeypox virus.

2. Centers for Disease Control and Prevention, "Updated Interim Case Definition for Human Case of Monkeypox," dated July 2, 2003 (available through [www.cdc.gov/ncidod/monkeypox](http://www.cdc.gov/ncidod/monkeypox)). FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

3. Centers for Disease Control and Prevention, "Questions and Answers About Monkeypox," dated July 7, 2003 (available through [www.cdc.gov/ncidod/monkeypox](http://www.cdc.gov/ncidod/monkeypox)).

4. Centers for Disease Control and Prevention, "Update: Multistate Outbreak of Monkeypox—Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003," *Morbidity and Mortality Weekly Report*, 52: 642-646 (July 11, 2003)

5. State of Colorado, Wildlife Commission, "Emergency Regulation," dated July 10, 2003.

6. State of Illinois, "Executive Order in Response to Orthopox Outbreak," dated June 7, 2003.

7. State of Indiana, Board of Animal Health, Emergency Rule, dated June 9, 2003.

8. State of Michigan, Department of Community Health, "Order Finding Imminent Danger to the Public Health and Requiring Corrective Action," dated June 13, 2003, and later amended on June 27, 2003.

9. State of North Dakota, State Board of Animal Health, "In the matter of: Monkeypox in Prairie Dogs and Gambian Giant pouched Rats," Order No. 2003-04, dated June 11, 2003.

10. State of Wisconsin, Department of Agriculture, Trade, and Consumer Protection, "Emergency Rule," dated June 9, 2003.

11. State of Wisconsin, Department of Health and Family Services, "Emergency Order - June 12, 2003," dated June 12, 2003.

12. Order dated June 11, 2003, signed by Julie Louise Gerberding, Director, Centers for Disease Control and Prevention, and Mark B. McClellan, Commissioner of Food and Drugs, titled "Joint Order of the Centers for Disease Control and Prevention and the Food and Drug Administration, Department of Health and Human Services."

13. 68 FR 36566, June 18, 2003.

14. Centers for Disease Control and Prevention, "Update: Multistate Outbreak of Monkeypox—Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003," *Morbidity and Mortality Weekly Report*, 52: 616-618, July 4, 2003, (describing how animal laboratory testing demonstrated that a Gambian giant pouched rat, three dormice, and two rope squirrels from an April 9, 2003, shipment of animals from Ghana were infected with the monkeypox virus).

15. North Carolina Department of Health and Human Services, "State Health Official Reminds Public Not to Release Prairie Dogs Into the Wild," dated June 19, 2003.

16. Colorado Division of Wildlife, "Wildlife Report: Black-Footed Ferrets Back in Colorado," dated November 19, 2001 (available at [www.dnr.state.co.us/cdr\\_news/wildlife/2001111985112.htm](http://www.dnr.state.co.us/cdr_news/wildlife/2001111985112.htm)).

17. Food and Drug Administration and Centers for Disease Control and Prevention, "Wild-to-Wild Translocation or Transportation of Prairie Dogs" (undated).

18. Centers for Disease Control and Prevention, "Interim Guidance to State and Local Governments for the Removal of State- and Locally Imposed Quarantine Orders and the Euthanasia of Animals Affected by the Monkeypox Outbreak," dated July 1, 2003.

19. Centers for Disease Control and Prevention, "Questions and Answers: Quarantine and Euthanasia of Animals Affected by the Monkeypox Outbreak," dated July 10, 2003.

20. Fish and Wildlife Service, "Notice to the Wildlife Import/Export Community," dated June 11, 2003 (describing import and export prohibitions on certain rodents, including any rodents from Africa, whether alive or dead, for any purpose).

21. Peeters, M., et al., "Risk to Human Health from a Plethora of Simian