Control of Communicable Diseases; Restrictions on African Rodents,
Prairie Dogs, and Certain Other Animals
OMB Control No. 0910-0519
Supporting Statement

A. Justification

1. Circumstances Necessitating Information Collection

As authorized by 42 U.S.C. 264 of the PHS Act, the Food and Drug Administration (FDA) is requesting OMB approval of the information collection requirement in "Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals, at 21 CFR 1240.63(a)(2)(ii). The regulation imposes certain restrictions on the capture, transport, sale, barter, exchange, distribution, and release into the environment of several African rodent species, prairie dogs, and other animals to prevent the establishment and spread of monkeypox, a communicable disease, in the United States.

We estimate that the total information collection would be 488 hours.

21 CFR 1240.63 - Reporting

Under 21 CFR 1240.63(a)(2)(ii)(A) and (B), an individual must submit a written request to seek permission 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 into the environment any of the following animals:

1Prairie dogs (*Cynomys* sp.),
2African Tree squirrels (*Heliosciurus* sp.),
3Rope squirrels (*Funisciurus* sp.),
4African Dormice (*Graphiurus* sp.),
5Gambian giant pouched rats (*Cricetomys* sp.),
6Brush-tailed porcupines (*Atherurus* sp.),
7Striped mice (*Hybomys* sp.), or
8Any other animal so prohibited by order of the Commissioner of Food and Drugs because of that animal's potential to transmit the monkeypox virus.

The request cannot seek written permission to sell, barter, or exchange, or offer to sell, barter, or exchange, as a pet, the animals listed above or any animal covered by an order by the Commissioner of Food and Drugs.

The request must state the reasons why an exemption is needed, describe the 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.

2. How, by Whom, and for What Purpose Information Used

We will use the information to decide whether to grant permission 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 into the environment any animal listed in 21 CFR 1240.63(a)(1) or covered by an order issued by the Commissioner of Food and Drugs.

3. Consideration of Information Technology

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

4. Efforts to Identify Duplication and Similar Information Already Available

FDA and CDC are the agencies authorized, under 42 U.S.C. 264, to make and enforce regulations to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States. Therefore, no duplication of data exists.

5. Small Business

The Small Business Administration (SBA) sets criteria by which it qualifies businesses as small entities. The SBA limit for small pet and pet supply stores is $6 million in revenues. Census Bureau data shows that about 6,500 retail pet store companies operate about 8,300 establishments in the United States. A substantial number of these firms (about 94%) have a single establishment with average annual revenues of about $356,000, thereby qualifying them as small businesses. It is unlikely that the total sales of all of the listed animals would represent a significant portion of total pet store sales. However, due to the lack of data on total sales of these animals, as well as the possibility that some pet stores may specialize in the small animals that are listed in this rule, we cannot rule out the possibility that the rule may have a significant impact on a substantial number of these small entities.

The SBA limit for small business qualification for trappers is $3.5 million or less in revenues. Prairie dog trappers would qualify as small businesses under this definition. For some trappers, the loss of profits due to the rule's prohibitions would likely represent a significant impact on their businesses; however, the rule's prohibitions have been in place sine 2004, so the potential loss in profits should have diminished over time.

We lack the data to determine the extent to which wholesalers and distributors of all small animals listed in this regulation would be affected. That being the case, we allow for the possibility that a substantial number of those that are affected may be small entities, and in some instances may incur significant impacts due to this rule.

The interim final rule requested public comment on the size and structure of those firms or persons involved in the trade of all animals listed in the regulation and the rule's effects on such firms and persons. A subsequent *Federal Register* notice (Tab C)

pertaining to the information collection provisions, pursuant to the Paperwork Reduction Act of 1995, also invited comment. Although we received some comments from individual firms, the comments provided little or no data concerning the size and structure of the affected pet trade. The incompleteness of data, as described previously, precludes us from developing quantitative estimates of the costs of this rule for each type of small entity.

6. Consequences of Less Frequent Information Collection and Technical or Legal Obstacles

Failure to submit the requests for written permission increases the likelihood that individuals will capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, release into the environment, import, or offer to import African rodents, prairie dogs, and certain other animals regardless of whether those animals are infected or could be become infected with the monkeypox virus. These activities, if left uncontrolled and not monitored by FDA, would make it more difficult to prevent the establishment or spread of the monkeypox virus in the United States.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

The reporting requirements in the regulation are consistent with the guidelines in 5 CFR 1320.5(d)(2). The regulation does not require any records to be kept.

The interim final rule does not require any person to submit requests to FDA more frequently than the quarterly basis described in § 1320.5(d)(2)(i).

8. Consultation Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment on the information collection provisions in the *Federal Register* of March 13, 2007. We received no comments.

9. Payment or Gift to Respondents

We did not provide any payment or gifts to respondents.

10. Confidentiality of Information

Information given to FDA would be subject to the statutes and regulations governing public disclosure of information as well as those pertaining to the protection of confidential and trade secret information. Therefore, assurances of confidentiality (beyond those already existing in federal law and FDA regulations) are unnecessary.

11. Sensitive Questions

No questions of a sensitive nature are asked.

12. Estimates of Burden Hours and Explanation

FDA's estimates are based on its current experience to date with the interim final rule. To estimate the number of respondents, we examined the number of requests and inquiries it received in fiscal year 2006. There were 122 requests, submitted by 65 individuals, in that time, and this figure represents a minor increase over the previous estimate of 120 annual responses. As we cannot determine whether the latest data indicates a trend towards more requests or is an anomaly, we have, in this submission, elected to increase our estimate to 122 requests. We also have revised the estimated number of respondents to 65 (from 120) and, as a result, adjusted the annual frequency per response to 1.88 (which represents 122 responses/65 respondents; the actual result is 1.8769, which we have rounded up to 1.88). Therefore, the total reporting burden under 21 CFR § 1240.63(a)(2)(ii)(A) and (B) will be 488 hours (122 responses x 4 hours per response = 488 hours).

Cost to Respondents: The regulation allows for persons wishing to seek exemptions from the rule's prohibitions by requesting written permission from FDA. We estimate that about 122 such requests would be made annually. We expect most requests to be made by animal relocation specialists or others involved in biological research or conservation efforts. These requests are estimated to take four hours to complete, although we believe that the actual average burden hours per response may be lower because we receive many requests from individuals who have some experience with the permit process and, therefore, are familiar with our requirements and expectations. We cannot confidently estimate an average wage for those seeking permission to transport listed animals, but, at a total annual burden of about 488 hours and assuming an average wage for respondents between $6.25 and $12.50 per hour, the total cost burden would range from $3,050 to $6,100.

ESTIMATED ANNUAL REPORTING BURDEN*

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total No. of Responses	Hours per Response	Total Hours
1240.63(a)(2)(ii)(A) and (B)	65	1.88	122	4	488
				Total	488

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

13. Annual Cost to Respondents

There are no total capital or start-up costs or service costs projected for this regulation.

14. Annual Cost to the Government

As we have gained more experience with the permit program, our resource costs to process and respond to each request now are estimated to be approximately 4.6 hours per response (down from the previous estimate of 6 hours per response) distributed across various staff levels. We estimate that the average grade level of these staff positions is GS-12.6, which, in the Washington-Baltimore-Northern Virginia locality (as established by the Office of Personnel Management), would be a wage rate of $36.36 per hour. The

administrative effort to process these requests would result in $20,405.23 (122 requests x 4.6 hours per request x $36.36 per hour = $20,405.23) in costs to FDA.

15. Changes in Burden

In our previous Paperwork Reduction Act submission to OMB, we estimated that 120 respondents would submit requests. As stated earlier, the data from fiscal year 2006 shows that we received 122 requests from 65 individuals. We cannot determine whether the minor increase in respondents indicates a trend towards more requests or is an anomaly, so we have adjusted the estimates to 65 respondents, 122 annual responses, and an average of 1.88 responses per respondent. The average hours per response remains the same at 4 hours, so the total is 488 total burden hours, or a change in 8 additional burden hours.

16. Statistical Reporting

Information collected under this requirement will not be published.

17. Exemption for Display of Expiration Date

The agency does not seek an exemption from displaying the expiration date.

18. Exemption to Certification Statement

N/A.