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 (Tab A), 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) (Tab B). The rule 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.

FDA estimates that the total information collection would be 480 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:

A. Prairie dogs (*Cynomys* sp.),
B. African Tree squirrels (*Heliosciurus* sp.),
C. Rope squirrels (*Funisciurus* sp.),
D. African Dormice (*Graphiurus* sp.),
E. Gambian giant pouched rats (*Cricetomys* sp.),
F. Brush-tailed porcupines (*Atherurus* sp.),
G. Striped mice (*Hybomys* sp.), or
H. Any 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

FDA 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. FDA considers it 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, FDA 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 surely 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.

FDA lacks the data to determine the extent to which wholesalers and distributors of all small animals listed in this regulation (including those that import animals and those that handle domestic animals) would be affected. That being the case, FDA allows 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 regulation 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. Although FDA 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 FDA 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 with the monkeypox virus. These activities, if left uncontrolled and not monitored by FDA and CDC, would increase the likelihood of the monkeypox virus becoming established and spreading 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), a 60-day notice for public comment on the information collection provisions was published in the **Federal Register** of February 19, 2004, (69 FR 7752) (Tab C). We received nearly 700 comments on the interim final rule and the notice that invited public comment on the proposed collection of information. Over 140 of these comments were submitted after February 19, 2004 (the date on which we published the notice concerning the collection of information), but the majority of these later comments apparently interpreted that notice as another opportunity to comment on the interim final rule's merits rather than comment on the collection of information itself. This notice simply announces that we are seeking renewal of OMB's paperwork approval for the interim final rule and addresses those comments regarding the collection of information. It is not an issuance of a final rule and we are not seeking additional comments on the interim final rule.

Of the few comments that may pertain to the collection of information, none agreed with the collection of information or the estimates themselves. Here we address the comments on the collection of information, not the comments on the substance of the rule itself.

Some comments claimed that we take 2.5 to 4 months to process a permit request. Of these comments, some also claimed that the permit process was too burdensome because State agencies had to be involved. One comment claimed that the permit process requires a person to describe the benefits that would result if we granted the permit and indicated that it is sometimes difficult to show a benefit.

We disagree with the comments for several reasons. First, we disagree with the claim that our permit process takes several months to complete. While permit requests vary in their complexity, and complex and incomplete requests may take more time to process, our records indicate that we respond to permit requests, on average, within 27 days (including weekends and holidays).

Second, although a person seeking a permit must also comply with all State and local requirements related to the handling and transport of animals subject to the interim final rule, nothing in the interim final rule's permit provision requires a person to contact State agencies as part of FDA's permit process. We may consult State agencies about a particular permit request, but this consultation does not create an information collection burden on the person requesting the permit. Furthermore, the interim final rule does not require a person seeking a permit to describe the benefit that would result if we granted their request. The interim final rule does require a person to explain why an exemption will not result in the spread of monkeypox in the United States, and this explanation can be derived from the facts accompanying the permit request. For example, the description of the animals involved (species, absence of contact with infected animals, the animals' origin) may help explain why the animals involved do not present a risk of having the monkeypox virus. The description of the precautions taken may help explain why there is no risk of spreading the monkeypox virus. In other words, the interim final rule does not require a person to show that a "benefit" would result if we granted the permit, but it does seek information to help us assess the risk associated with the request.
Other comments appeared to address the estimated number of respondents or our data. One comment stated that it believed the estimated number of respondents (i.e., persons who would request a permit) is too low, although it offered no different estimates itself. The comment further stated that there are people who are ignoring the rule or are unaware of the rule, but offered no estimates. Another comment declared "there are major flaws with the data collection in this docket," but did not discuss the permit process or any specific estimate.

As we explained in the February 19, 2004 notice, we based our estimates on our experience with the permit process, including the experience of those submitting permit requests (see 69 FR 7752). We have no reasonable basis for adjusting our estimates to reflect the possibility that persons are either intentionally or unintentionally failing to seek permits, and the comments offered none. Consequently, in the absence of any new data or conflicting estimates, we decline to revise our estimates.

9. Payment or Gift to Respondents

FDA 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 experience to date with the June 11, 2003, order and on similar requests under FDA regulations. To estimate the number of respondents, FDA examined the number of requests and inquiries it has received since the June 11, 2003, order. FDA has received fewer than 10 requests, and most requests involved requests to move an animal from one location to another. FDA also has received several inquiries asking when the order might be lifted or whether it would consider exceptions to the order. As the agency cannot predict how the monkeypox outbreak will be resolved, FDA will tentatively estimate that 120 respondents would be affected. Furthermore, based on our experience with submissions seeking exemptions or waivers, the agency will tentatively estimate that each respondent will need two 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 480 hours (120 respondents x 4 hours per response = 480 hours).

Cost to Respondents: The regulation would allow for persons wishing to seek exemptions from the rule's prohibitions by requesting written permission from FDA. FDA has tentatively estimated that about 120 such requests would be made to FDA annually. The agency expects most requests to be made by animal relocation specialists or others involved in biological research or conservation efforts. These requests are estimated to take two hours to complete. FDA cannot confidently estimate an average wage for those seeking permission to transport listed animals, but at a total annual burden of about 480 hours, the total cost burden would range from $3,000 to $6,000.

ESTIMATED ANNUAL REPORTING BURDEN*

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)	120	1	120	4	480
				Total	480

* 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

FDA resource costs to process and respond to each request are estimated to total about 6 hours distributed across various staff levels. FDA estimates that the average pay level of

these staff positions is approximately $37/hour. The administrative effort to process these requests would result in about $13,300 (60 requests x 6 hours per request x $37 per hour = $13,320) in costs to FDA.

15. Changes in Burden

As stated in the February 19, 2004 notice, FDA adjusted the estimated burden hours from 120 hours to 480 hours. Two factors accounted for this increase. First, the estimated number of respondents was doubled from 60 to 120, based on FDA's experience with the number of requests it had received. Second, based on its experience with the requests submitted thus far and the parties submitting the requests, FDA increased the estimated burden hours per response from 2 hours to 4 hours. Thus, the interim final rule had projected a total burden of 120 hours, based on an estimated 60 respondents and 2 burden hours per response (60 respondents x 1 request per respondent x 2 hours per response = 120 hours for all requests), and FDA now estimates the total burden hours to be 480 (120 respondents x 1 request per respondent x 4 hours per response = 480 hours for all requests).

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

The agency does not request any exemption from the certification statement identified in Item 19 of form OMB Form 83-I.