2. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Additional Requested Information.

f. Measures of Effectiveness.

3. Financial status report, no more than 90 days after the end of the budget period.

4. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770–488–2700.

For program technical assistance, contact: Elizabeth Marum, Ph.D., Project Officer, Global Aids Program [GAP], Kenya Country Team, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention [CDC], PO Box 606 Village Market, Nairobi, Kenya, telephone: 256–20–271–3008, e-mail: *emarum@cdcnairobi.mimcom.net.*

For budget assistance, contact: Diane Flournoy, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770–488–2072, e-mail: *dmf6@cdc.gov.*

Dated: July 2, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–15602 Filed 7–8–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0049]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 9, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals (OMB Control Number 0910–0519)—Extension

Under § 1240.63(a)(2)(ii) (21 CFR 1240.63(a)(2)(ii)), 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:

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

The request may not seek written permission to sell, barter, or exchange, or offer to sell, barter, or exchange, as a pet, the animals listed previously or any animal covered by an order of the Commissioner.

The request must state, among other things, the reasons why an exemption is needed, describe the animals involved, and explain why an exemption will not result in the spread of monkeypox within the United States.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total No. of Responses	Hours per Response	Total Hours
1240.63(a)(2)(ii)	120	1	120	4	480

[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 interim final rule. To estimate the number of respondents, we examined the number of requests we have received since the June 11, 2003, order. FDA has received approximately 65 requests in a 7-month period, and most requests involved requests to move an animal from one location to another. 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 FDA's experience with requests submitted thus far, and the parties submitting those requests, the agency estimates that each respondent will need 4 hours to complete its request for an exemption. Therefore, the total reporting burden

under § 1240.63(a)(2)(ii) will be 480 hours (120 respondents x 4 hours per response = 480 hours).

In the **Federal Register** of February 19, 2004 (69 FR 7752), FDA published a 60-day notice requesting public comment on the information collection provisions. 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 1/2 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. 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.

Dated: July 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15658 Filed 7–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0103]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Special Protocol Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 9, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Special Protocol Assessment—(OMB Control Number 0910–0470)—Extension

In the **Federal Register** of March 22, 2004 (69 FR 13304), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

The ''Guidance for Industry on Special Protocol Assessment'' (69 FR 13304) describes agency procedures to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the agency to act on such requests. The guidance provides information on how the agency will interpret and apply