DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0049]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements establishing restrictions on the import, capture, transport, sale, barter, exchange, distribution, and release of African rodents, prairie dogs, and certain other animals.

DATES: Submit written or electronic comments on the collection of information by April 19, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Control of Communicable Diseases; African Rodents and Other Animals That May Carry the Monkeypox Virus—21 CFR 1240.63 (OMB Control Number 0910–0519)—Extension

Under 21 CFR 1240.63(a)(2)(ii), an individual must submit a written request to seek permission to capture, offer to capture, transportation, 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 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 previously 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, 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:

ESTIMATED ANNUAL REPORTING BURDEN[1]

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)	120	1	120	4	480
Total					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 21 CFR 1240.63(a)(2)(ii) will be 480 hours (120 respondents x 4 hours per response = 480 hours).

Dated: February 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3485 Filed 2–18–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0136]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adoption of the FDA Food Code By Local, State, and Tribal Governments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Adoption of the FDA Food Code by Local State and Tribal Governments,'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 2, 2003 (68 FR 56844), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0448. The approval expires on January 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: February 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3486 Filed 2–18–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0360]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information Program on Clinical Trials for Serious or Life-threatening Diseases: Maintaining of a Databank

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 March 22, 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: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION:

I. Background

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

Information Program on Clinical Trials for Serious or Life-threatening Diseases: Maintaining a Databank —(OMB Control Number 0910–0459)—Extension

In the **Federal Register** of March 18, 2002 (65 FR 12022), FDA issued a guidance to industry on recommendations for investigational new drug application (IND) sponsors on submitting information about clinical trials for serious or life-threatening diseases to the Clinical Trials Data Bank developed by the National Library of Medicine, National Institutes of Health (NIH). This information is especially important for patients and their families seeking opportunities to participate in clinical trials of new drug treatments for serious or life-threatening diseases. The guidance describes the following three collections of information: (1) Mandatory submissions, (2) voluntary submissions, and (3) certifications.

II. Mandatory Submissions

Section 113 of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public Law 105–115) requires that sponsors shall submit information to the Clinical Trials Data Bank when the clinical trial: (1) Involves a treatment for a serious or life-threatening disease and (2) is intended to assess the effectiveness of the treatment. The final guidance discusses how sponsors can fulfill the requirements of section 113 of the Modernization Act. Specifically, sponsors should provide the following: (1) Information about clinical trials, both federally and privately funded, of experimental treatments (drugs, including biological products) for patients with serious or life-threatening diseases; (2) a description of the purpose of the experimental drug; (3) patient eligibility criteria; (4) the location of clinical trial sites; and (5) a point of contact for patients wanting to enroll in the trial. Senate 1789, ''Best Pharmaceuticals for Children Act'' (BPCA) (Public Law 107–109) established a new requirement for the Clinical Trials Data Bank mandated by section 113 of the Modernization Act. Information submitted to the data bank must now include ''* * * a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children.'' The final guidance will be updated to include a discussion of how sponsors can fulfill the BPCA requirements.

III. Voluntary Submissions

Section 113 of the Modernization Act also specifies that sponsors may voluntarily submit information pertaining to results of clinical trials, including information on potential toxicities or adverse effects associated with the use or administration of the investigational treatment. Sponsors may also voluntarily submit studies that are not trials to test effectiveness, or not for serious or life-threatening diseases, to the Clinical Trials Data Bank.