DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 1240

[Docket No. 2003N–0400]

RIN 0910–ZA21

Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; supplement and partial reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the interim final rule on the capture, transport, sale, barter, exchange, distribution, and release of African rodents, prairie dogs, and certain other animals, which was published in the Federal Register of November 4, 2003 (68 FR 62353). FDA is taking this action because it is adding new information, primarily in the form of peer-reviewed scientific literature, to the administrative record. FDA is reopening the comment period for 30 days for the sole purpose of inviting public comments on the information being added to the administrative record.

DATES: Submit written or electronic comments by March 23, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2003N–0400 and/or RIN number 0910–ZA21, by any of the following methods:

Electronic Submissions
Submit electronic comments in the following ways:

Written Submissions
Submit written submissions in the following ways:
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the ADDRESSES portion of this document under ELECTRONIC SUBMISSIONS.

Instructions: All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to http://www.fda.gov/ohrms/dockets/dockets/default.htm, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.fda.gov/ohrms/dockets/dockets/default.htm, including any personal information provided. For additional information about the virus and how the monkeypox outbreak in the United States, including information about the virus and how the disease affected or affects humans and animals, be posted without change to the Federal Register.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Phone: 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 4, 2003 (68 FR 62353), the Centers for Disease Control and Prevention (CDC) and FDA issued an interim final rule to establish new restrictions and modify existing restrictions on the import, capture, transport, sale, barter, exchange, distribution, and release of African rodents, prairie dogs, and certain other animals in order to prevent the spread of monkeypox, a communicable disease, in the United States. The CDC regulation is codified at 42 CFR 71.56, and FDA’s regulation is codified at 21 CFR 1240.63.

Since the publication of the interim final rule in the Federal Register, additional scientific information has appeared regarding the 2003 monkeypox outbreak. In general, the scientific information adds to our knowledge about the 2003 monkeypox outbreak in the United States, including information about the virus and how the disease affected or affects humans and animals.

FDA is adding the following documents to the administrative record for the interim final rule:

I. Background

A. What Are the Clean Air Act Requirements for I/M Programs?

The Clean Air Act (CAA) requires certain states to implement an enhanced inspection and maintenance (I/M) program to detect excess emissions from gasoline-fueled motor vehicles which exhibit excessive emissions of certain air pollutants. The enhanced I/M program is intended to help states meet federal health-based national ambient air quality standards (NAAQS) for ozone and carbon monoxide by requiring vehicles with excess emissions to have their emissions control systems repaired. Section 182 of the CAA requires I/M programs in those areas of the nation that are most impacted by carbon monoxide and ozone pollution. Section 184 of the CAA also created an “Ozone Transport Region” (OTR) which geographically includes the 11 states from Maryland to Maine (including all of New York State) and the District of Columbia Consolidated Metropolitan Statistical Area. Depending on the severity of the nonattainment designation(s) and/or geographic location within the OTR, EPA’s regulations under 40 CFR 51.350 outlines the appropriate motor vehicle I/M requirements.

As a result of the 1-hr ozone nonattainment designations, New York State’s 62 counties were divided into two separate I/M areas. The “downstate” 9-county New York Metropolitan Area (NYMA), which includes New York City (Bronx, Kings, New York, Richmond, and Queens Counties), Long Island (Nassau and Suffolk Counties), and Westchester and Rockland Counties, has been classified as a high enhanced I/M area. On January 1, 1998, New York began implementing a high enhanced I/M program (New York refers to this program as its NTEST program) in the NYMA. By May 1999, this enhanced I/M program was fully functional for the entire NYMA.

The remaining 53 “Upstate” counties of New York State were classified as a low enhanced I/M area. Since 1998, the Upstate I/M area featured annual anti-tampering visual inspections including a gas cap presence check.

Since all of New York State is included within the OTR, additional I/M requirements are mandated in the more populated counties of Upstate New York pursuant to 40 CFR 51.350(a). Section 51.350(a)(1) provides that,