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:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- 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/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/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

1. Anderson, M.G., et al., ''A Case of Severe Monkeypox Virus Disease in an American Child: Emerging Infections and Changing Professional Values,'' *Pediatric Infectious Disease Journal*, 2003; 22:1093–1096.

2. Bernard, S.M. and Anderson, S.A., ''Qualitative Assessment of Risk for Monkeypox Associated with Domestic Trade in Certain Animal Species, United States'' *Emerging Infectious Diseases*, 2006; 12: 1827–1833.

3. Di Giulio, D.B. and Eckburg, P.B., ''Human Monkeypox: An Emerging Zoonosis,'' *Lancet Infectious Diseases*, 2004; 4:15–25.

4. Fleischauer, A.T., et al., ''Evaluation of Human-to-Human Transmission of Monkeypox from Infected Patients to Health Care Workers,'' *Clinical Infectious Diseases*, 2005; 40:689–694.

5. Guarner, J., et al., ''Monkeypox Transmission and Pathogenesis in Prairie Dogs,'' *Emerging Infectious Diseases*, 2004; 10:426–431.

6. Hammarlund, E., et al., ''Multiple Diagnostic Techniques Identify Previously Vaccinated Individuals With Protective Immunity Against Monkeypox,'' *Nature Medicine*, 2005; 11:1005–1011.

7. Huhn, G.D., et al., ''Clinical Characteristics of Human Monkeypox, and Risk Factors for Severe Disease,'' *Clinical Infectious Diseases*, 2005; 41:1742–1751.

8. Huhn, G.D., et al., ''Monkeypox in the Western Hemisphere,'' *New England Journal of Medicine*, 2004; 350:1790–1791.

9. Jamieson, D.J., et al., ''Emerging Infections and Pregnancy: West Nile Virus, Monkeypox, Severe Acute Respiratory Syndrome, and Bioterrorism,'' *Clinics in Perinatology*, 2005; 32:765–776.

10. Kile, J.C., et al., ''Transmission of Monkeypox Among Persons Exposed to Infected Prairie Dogs in Indiana in 2003,'' *Archives of Pediatrics and Adolescent Medicine*, 2005; 159:1022–1025.

11. Likos, A.M., et al., ''A Tale of Two Clades: Monkeypox Viruses,'' *Journal of General Virology*, 2005; 86:2661–2672.

12. Nalca, A., et al., ''Reemergence of Monkeypox: Prevalence, Diagnostics, and Countermeasures,'' *Clinical Infectious Diseases*, 2005; 41:1765–1771.

13. Reed, K.D., et al., ''The Detection of Monkeypox in Humans in the Western Hemisphere,'' *New England Journal of Medicine*, 2004; 350:342–350.

14. Reynolds, Gretchen, ''Why Were Doctors Afraid to Treat Rebecca McLester?'' New York Times, April 18, 2004.

15. Reynolds, M.G., et al., ''Clinical Manifestations of Human Monkeypox Influenced by Route of Infection,'' *Journal of Infectious Diseases*, 2006; 773–780.

16. Sejvar, J.J., et al., ''Human Monkeypox Infection: A Family Cluster in the Midwestern United States,'' *Journal of Infectious Diseases*, 2004; 190:1833–1840.

17. Xiao, S., et al., ''Experimental Infection of Prairie Dogs with Monkeypox Virus,'' *Emerging Infectious Diseases*, 2005; 11:539–545.

II. Comments

Through this document, FDA is announcing the addition of the previous materials to the administrative docket and inviting comment limited to these publications. FDA believes that a 30–day comment period is sufficient in this case, as the agency is specifically limiting its reopening of the comment period to comments on how the agency should consider the information being added to the administrative docket in relation to FDA's interim final rule. Comments are invited, and will be considered, only to the extent they are focused on the specific information being added to the record of FDA's interim final rule.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the documents listed above. Submit a single copy of electronic comments or two copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 9, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2857 Filed 2–20–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Docket No. EPA–R02–OAR–2006–0685, FRL–8275–5]

Approval and Promulgation of Implementation Plans; New York; Motor Vehicle Enhanced Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is approving a revision to the State Implementation Plan (SIP) for New York's motor vehicle enhanced inspection and maintenance (I/M) program which includes the adoption of a statewide On-Board Diagnostic (OBD) program. New York has made revisions to Title 6 of the New York Codes, Rules and Regulations (NYCRR), Part 217, ''Motor Vehicle Enhanced Inspection and Maintenance Program Requirements,'' and Title 15 NYCRR Part 79, ''Motor Vehicle Inspection Regulations,'' to comply with EPA regulations and to improve performance of its I/M program. The intended effect of this action is to maintain consistency between the State-adopted rules and the federally approved SIP and to approve a control strategy that will result in emission reductions that will help achieve attainment of the national ambient air quality standard for ozone.

DATES: *Effective Date:* This rule will be effective March 23, 2007.

ADDRESSES: EPA has established a docket for this action under the Federal Docket Management System (FDMS) which replaces the Regional Materials in EDOCKET (RME) docket system. The new FDMS is located at *www.regulations.gov* and the docket ID for this action is EPA–R02–OAR–2006–0685. All documents in the docket are listed in the FDMS index. Publicly available docket materials are available either electronically in FDMS or in hard copy at the Environmental Protection Agency, Region 2 Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007–1866. Copies of the documents relevant to this action are also available for public inspection during normal business hours, by appointment at the Air and Radiation Docket and Information Center, Environmental Protection Agency, Room 3334, 1301 Constitution Avenue, NW., Washington, DC; and the New York State Department of Environmental Conservation, Division of Air Resources, 625 Broadway, Albany, New York 12233.

FOR FURTHER INFORMATION CONTACT: Kirk J. Wieber, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–3381.

SUPPLEMENTARY INFORMATION:

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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 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 regulation 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 NYTEST 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,