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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 1240

[Docket No. 2003N-0400]

RIN 0910-ZA21

Centers for Disease Control and Prevention

42 CFR Part 71

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

AGENCIES: Centers for Disease Control and Prevention, Food and Drug Administration (HHS).

ACTION: Interim final rule; opportunity for public comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are issuing this interim final rule to amend their regulations 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. We are taking this action to prevent the spread of monkeypox, a communicable disease, in the United States.

DATES: The interim final rule is effective on November 4, 2003. Submit written or electronic comments on this interim final rule by January 20, 2004.

ADDRESSES: For FDA: Send written comments on the rule and on the information collection to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

For CDC: Send written comments on the information collection to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Rd., MS E11, Atlanta, GA 30333. Comments on the rule itself should be sent to FDA's Division of Dockets Management (see FDA addresses).

FOR FURTHER INFORMATION CONTACT:

For information regarding FDA: Philip L. Chao, Office of Policy and Planning (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0587.

For information regarding CDC: James E. Barrow, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Mailstop C-14, 1600 Clifton Rd., Atlanta, GA 30333, 404-498-1600.

SUPPLEMENTARY INFORMATION:

I. What Is Monkeypox, and How Did It Spread in the United States?

Monkeypox is a rare, zoonotic, viral disease that occurs primarily in the rain forest countries in central and west Africa. (A zoonotic disease is a disease of animals that can be transmitted to humans under natural conditions.) The illness was first noted in monkeys in 1958 (which explains its name), but, in Africa, serologic evidence of monkeypox infection has been found in many other species, including some species of primates, rodents, and lagomorphs (which includes such animals as rabbits). African rodents are considered to be the most likely natural host of the monkeypox virus (Ref. 1).

In humans, monkeypox is marked by rashes that are similar to those seen in smallpox; other signs and symptoms include a temperature at or above 99.3 degrees, chills and/or sweats, headache, backache, lymphadenopathy (a disease of the lymph nodes), sore throat, cough, and shortness of breath (Ref. 2). The disease's incubation period is approximately 12 days (Ref. 3). In Africa, monkeypox has a mortality rate in humans ranging from 1 to 10 percent.

As of July 8, 2003, there have been 35 laboratory-confirmed cases of monkeypox in people in the United States, and about another three dozen suspect and probable cases under investigation, in Illinois, Indiana, Kansas, Ohio, Missouri, and Wisconsin (Ref. 4). As of July 11, 2003, 16 persons

were reported to have been hospitalized; however, some of these hospitalizations were for isolation purposes unrelated to illness. Among those hospitalized, two were children who required intensive care, one for severe monkeypox-associated encephalitis (encephalitis is an inflammation of the brain), and one with profound painful cervical and tonsillar adenopathy (adenopathy refers to an enlargement of the glands) and diffuse pox lesions, including lesions in the oropharynx. Both children recovered from their illness.

In the United States, individuals apparently began contracting monkeypox in early May, 2003, primarily as a result of contact with prairie dogs that had contracted monkeypox from diseased African rodents. Investigations indicate that a Texas animal distributor imported a shipment of approximately 800 small mammals from Ghana on April 9, 2003, and that shipment contained 762 African rodents, including rope squirrels (*Funisciurus* sp.), tree squirrels (*Heliosciurus* sp.), Gambian giant pouched rats (*Cricetomys* sp.), brushtail porcupines (*Atherurus* sp.), dormice (*Graphiurus* sp.), and striped mice (*Hybomys* sp.). Some animals were infected with monkeypox, and CDC laboratory testing confirmed the presence of monkeypox in several rodent species, including one Gambian giant pouched rat, three dormice, and two rope squirrels (Ref. 4). Of the 762 rodents from the original shipment, 584 have been traced to distributors in six states. A total of 178 African rodents could not be traced beyond the point of entry in Texas because records were not available (Ref. 4). The number of animals traced may change as the investigation continues.

II. What Actions Have Been Taken to Prevent the Spread of Monkeypox?

Non-native animal species, such as the African rodents, can create serious public health problems when they introduce a new disease, such as monkeypox, to the native animal and human populations. The transportation, sale, or distribution of an infected animal, or the release of an infected animal into the environment can result in the further spread of disease to other animal species and to humans.

Several States have issued orders or emergency rules to prohibit the