



PET INDUSTRY
JOINT ADVISORY
COUNCIL

5749 04 JAN 22 10:38
1220 19th Street, N.W.
Suite 400
Washington, DC 20036
Telephone: 202-452-1525
Fax: 202-293-4377

January 20, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2003N-0400 – Control of Communicable Diseases; Restrictions on
African Rodents, Prairie Dogs, and Certain Other Animals

Gentlemen/Ladies:

The Pet Industry Joint Advisory Council (PIJAC) submits herein its comments on the interim final rule regarding import, capture, transport, sale, barter, exchange, distribution and release of African rodents, prairie dogs, and other specified animals subject to the rule. For the reasons stated, PIJAC endorses the proposed action by FDA to lift the temporary ban, but believes that certain amendments to both FDA and CDC authority under this rule are called for.

I. Statement of Interest

PIJAC is the largest pet trade association in the world, representing the interests of the entire pet industry throughout the United States. PIJAC's thousands of members include associations, organizations, corporations and individuals involved in the commercial pet trade, and entailing the breeding, import, export, distribution, wholesale and retail sale of companion animals, including animals which are and may be subject to restrictions imposed under the final interim rule. PIJAC's members will be directly and substantially impacted by this rulemaking. PIJAC's mission is to ensure the availability of pets to the public and, to the extent this rulemaking impacts the ability of members of the public to ship and receive pet animals, these comments speak to the interests of such public as well.

II. Introduction

With the appearance of the Monkeypox virus in the United States, PIJAC immediately began an aggressive campaign to coordinate with affected federal and state agencies, to inform and educate its members on implications of the outbreak and governmental action in response thereto, and to assure that appropriate steps were taken by those in the pet trade to contain Monkeypox. PIJAC was requested to appear before Congress for testimony, and did so, advocating the temporary ban that FDA shortly thereafter implemented on transporting species of animals suspected to be infected with the virus. PIJAC's actions following the appearance of this virus in the U.S. were consistent with its longstanding commitment to work responsibly with government to promote the health and

2003 N-0400

C69

safety of the public, and of companion animals themselves, in the commercial pet trade. At the same time, PIJAC opposes onerous rules that are overly broad, unduly burdensome, unsupported by scientific evidence, or otherwise not in the public interest. Our comments on this rulemaking are made in this same vein.

III. Domestic Ban

With regard to the domestic ban on the transport, distribution or other dissemination of certain listed species, PIJAC endorses FDA's proposed intent to revoke 21 CFR 1240.63 in January 2004, assuming no additional evidence becomes available before that time indicating further significant risk of Monkeypox infection in the U.S. When we advocated a ban on transport of prairie dogs, we emphasized that it should be temporary in nature. FDA's approach of doubling the estimated incubation period was a sound method of assuring that Monkeypox had been contained, and continuation of the ban beyond this period would be undesirable and inappropriate.

If, for whatever reason, FDA fails to lift the ban, PIJAC would advocate further consideration of appropriate measures to address concerns, rather than adoption of a permanent ban. Based upon FDA's own evaluation, the permanent ban is not justified. PIJAC concurs. Thus, if the ban is not lifted altogether, we would specifically recommend that FDA solicit the participation of the pet trade and other interested parties in crafting an appropriate response.

Again, assuming that 21 CFR 1240.63 is revoked, our additional comments on this regulation become moot. PIJAC believes that fashioning the interim final rule consistent with the temporary rule was appropriate. Additional language, however, authorizing the agency to "take any other action necessary to prevent the spread of the monkeypox virus" may be excessive. While PIJAC recognizes the need for FDA to take expeditious action with regard to the potential spread of Monkeypox, we nevertheless believe that regulatory authority should not be open-ended but rather, by its nature, should state with particularity the scope of the agency's powers.

IV. Import Ban

With regard to CDC's prohibition on imports of African rodents, pursuant to 42 CFR 71.56, PIJAC reiterates its concern about expansive regulatory authority that appears to carry no limitations on agency action. Specifically, the agency's authority to "take any other action necessary to prevent the spread of the monkeypox virus" appears to grant CDC unlimited and unconstrained powers to take any action so long as it is predicated on containing monkeypox. Again, PIJAC recognizes the need for CDC to take expeditious action with regard to Monkeypox, but believes it inappropriate for an agency to invoke unfettered regulatory authority.

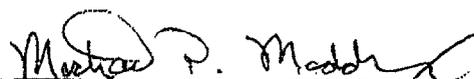
V. Conclusion

As a general proposition, PIJAC endorses this rulemaking as an appropriate agency response to the Monkeypox virus. We do feel, however, that regulatory language should be crafted with fair specificity and generally oppose open-ended authority. PIJAC emphasizes that FDA's stated intent to revoke 21 CFR 1240.63 is appropriate, but that if such action is not adopted, then a permanent ban would be a poor alternative. In light of any new information influencing FDA's decision in this

regard, the agency should revisit the question of remedial action and involve industry members in addressing it.

PIJAC thanks FDA and CDC for their due consideration of these comments.

Respectfully Submitted,
Pet Industry Joint Advisory Council



By: Michael P. Maddox
Director of Legislative Affairs