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Richard J. Fife
8171 Valley Vista Drive
Hereford, Arizona 85615

Re: Docket No. 98P-0680/CP

Dear Mr. Fife:

This letter is in response to your citizen petition dated August 5, 1998, and follow-up letter of August 25, 1999, in which you requested that the Food and Drug Administration (FDA) amend 21 CFR 1240.62, a regulation that prohibits the sale and distribution of small turtles and viable turtle eggs, to allow the sale of 1) viable turtle eggs and turtles with a carapace length of less than four inches to persons eighteen years of age or older and 2) live turtles of the species *Trachemys scripta elegans* (red-eared slider turtles) under four inches. In accordance with 21 CFR 10.30 (e) (3), this letter is to advise you that the FDA, for the reasons stated below, is denying your petition.

I. Background

A. Regulatory History of 21 CFR 1240.62

In the early 1970s, the pet industry estimated that 4% of families in the U.S. owned turtles.¹

During the same period, an estimated 14% of all cases of Salmonella infections (280,000 cases) were attributed to exposure to turtles.² Most of the cases reported occurred among young children who were infected following direct contact with Salmonella-contaminated turtles or Salmonella-contaminated turtle water.³

On April 7, 1972, the Administrator of the Health Services and Mental Health Administration with the approval of the Commissioner of Food and Drugs ("Commissioner") proposed to amend Part 71 (Foreign Quarantine) and Part 72 (Interstate Quarantine) of Title 42 of the Code of Federal Regulations (37 FR 7005) (copy enclosed). The proposal was to 1) provide a general prohibition on the importation of small pet turtles, tortoises, and terrapins, and 2) set bacteriological standards for such animals in interstate commerce. The final rule was published on November 18, 1972 (37 FR 24670) (copy enclosed). The rule required that turtles held for sale in interstate commerce be certified as Salmonella-free.

¹Centers for Disease Control, Reptile-Associated SalmonellosisB Selected States, 1994-95, Morbidity and Mortality Wkly. Rep. 347 (1995).

²Lamm, Steven H., et al., *Turtle-Associated Salmonellosis: I. An Estimation of the Magnitude of the Problem in the United States 1970-71*, 95 Am.J.Epidemiology 511 (1972).

³Cohen, Mitchell L. et al., *Turtle-Associated Salmonellosis in the United States: Effect on Public Health Action, 1970 to 1976*, 243 J.Am.Med.Ass'n 1247 (1980).

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However, certification proved ineffective in preventing Salmonella-contaminated turtles from reaching pet owners. A survey conducted by the Centers for Disease Control (CDC) between December 1972 and December 1973 established that 54% of the turtles were contaminated by Salmonella when retested some time subsequent to certification (40 FR 22543; May 23, 1975). Therefore, in 1975, the FDA through rulemaking imposed a ban on the interstate and intrastate sale and distribution of turtles having a carapace length of less than four inches in the United States (40 FR 22545; May 23, 1975) (copy enclosed). CDC estimates that this measure has prevented approximately 100,000 cases of salmonellosis annually.⁴ The final rule also provided several exceptions to the ban, including an exception for bona fide scientific, educational, or exhibitional purposes (21 CFR 1240.62(d)(1)).

B. Salmonellosis

The ban on the sale of small turtles under the provisions of the Public Health Service Act helps prevent the interstate and intrastate spread of communicable disease. Turtles are particularly well adapted hosts for Salmonella bacteria. For example, contaminated breeding and holding environments and transovarian transmission (infection of the egg) serve to perpetuate the transmission cycle in turtles (37 FR 24671; November 13, 1972). The ban is a necessary public health measure not only for protecting children from salmonellosis, but also other individuals who are at risk of salmonellosis (e.g., immuno-compromised individuals, the debilitated, and the elderly).⁵ Salmonella bacteria, which are carried by turtles, are the causative agent in salmonellosis, which is manifested by sudden onset of headache, abdominal pain, diarrhea, nausea, dehydration, and vomiting. Deaths are uncommon, except in the very young and the risk groups mentioned above. People can become infected by ingesting Salmonella after handling a turtle or objects contaminated by a turtle and then failing to wash their hands properly or by washing a turtle cage in the kitchen sink or bathtub, without subsequently properly sanitizing the tub before human use.⁶ Your petition does not challenge the effectiveness of the ban on selling turtles with a carapace length of less than four inches or viable turtle eggs in reducing cases of salmonellosis in children.

II. Response to Petition

A. Proposed 21 CFR 1240.62(d)(5)

Your amended petition requests that 21 CFR 1240.62 be amended as follows:

§ 1240.62(d)(5). The sale, holding for sale, and distribution of live turtles and viable turtle eggs produced or captive bred in the USA (but not to include *Trachemys scripta elegans*, red-eared slider) for the sale to or the distribution to adults 18 years old or older. A sign must be posted in a conspicuous location where turtles are offered for sale that states:
"Turtles with a carapace length of less than 4 inches pose a risk to small children, are not

⁴Centers for Disease Control, Reptile-Associated SalmonellosisB Selected States, 1994-95, Morbidity and Mortality Wkly. Rep. 347 (1995).

⁵Bradley, T., Angulo, F.J., Mitchell, M., *Public Health Education on Salmonella Spp and Reptiles*, 219 JAVMA 754-55 (2001), and Glaser, C.A., Angulo, F.J., and Rooney, J.A., *Animal-Associated Opportunistic Infections Among Persons Infected With the Human Immunodeficiency Virus*, 18 Clin.Infec.Dis. 14-24 (1994).

⁶Centers for Disease Control, Reptile-Associated SalmonellosisB Selected States, 1996-98, Morbidity and Mortality Wkly. Rep. 1009 (1999).

intended as pets for children, and cannot be sold to minors under the age of 18 years old. The highest sanitary measures must be taken, when handling turtles to reduce the possible risk of Salmonella." A similar statement and information sheet [approved by the FDA] describing the risk of keeping baby turtles and sanitary measures recommended to reduce the risk of contracting Salmonella from baby turtles must be provided to the purchaser of any turtle under four inches.

The FDA previously has addressed a minimum age standard for purchasing turtles with a carapace length of less than four inches. Comments to the November 18, 1972, and May 23, 1975, rulemakings raised the same issue of adding an exception for adults so that anyone 18 years and older could purchase pet turtles. The Commissioner found "that the greatest [public health] protection can be achieved by controlling the source of possible human infections." (40 FR 22545; May 23, 1975). The Commissioner concluded that there could be no general exception for adults because many turtles bought by adults could be taken home and given directly to children. (40 FR 22545; May 23, 1975). In fact, you recognize the potential for danger to children. In your original petition's statement of grounds unfavorable to your amendment, you state: "This amendment may be used by some to hide the distribution of live turtles to children and others under the age of 18." (See Petition, p.4).

You state several grounds for your proposed 21 CFR 1240.62(d)(5) exception. A listing of those grounds and the FDA's responses to them follows.

1. "Higher Standard" in Turtle Handling

You contend that "[t]he keeping of turtles has progressed to a much higher standard than in 1975 when the regulation was first implemented. There is an abundance of information available for the husbandry of turtles including the sanitary measures necessary to reduce the risk of Salmonella."

Although you argue that there is a "higher standard" in the keeping of turtles, you do not provide any discussion of this standard and precisely how it differs from the standard present in 1975.

Further, your petition provides no data or other evidence as to whether this "higher standard" of turtle keeping is known and understood beyond those individuals and groups that own turtles for bona fide scientific, educational, or exhibitional purposes. Without further information, the FDA cannot assume that the general public (whom 21 CFR 1240.62 is intended to protect) has knowledge of this "higher standard" of turtle keeping. You do not consider that while there was adequate information available to the public before 1975 about sanitary measures to reduce the risk of turtle-related salmonellosis, this fact did not prevent the occurrence of thousands of salmonellosis cases.⁷ Finally, you have provided no evidence to show that your amendment would prevent the occurrence of salmonellosis as effectively as the current ban. Therefore, this argument is not persuasive support for your proposed amendment because it provides no

⁷Lamm, S.H., Taylor, A., Gangarosa, E.J., Anderson, H.W., Young, W., Clark, M.H., Bruce, A.R., *Turtle-Associated Salmonellosis: An Estimation of the Magnitude of the Problem in the United States, 1970-1971*, 95(6) *Am.J.Epidemiology* 511-517 (1972), and *Turtles, Tortoises, Terrapins, Sale and Shipment Curbs*, 39 *Fed. Reg.* 18463, 18465-66 (May 28, 1974) (list of warnings and safety instructions for handling turtles).

evidence that the general public is aware of and will consistently follow careful sanitary practices when keeping turtles.

2. Turtles as an "Adult" Hobby

Your petition states that: "[k]eeping of turtles has become an adult hobby. Turtle organizations have sprung up all over the country to educate the public concerning the keeping, care, and conservation of turtles and tortoises."

This argument does not provide sufficient justification for amending 21 CFR 1240.62. This regulation already provides an exception in 21 CFR 1240.62(d)(1) for turtles owned for bona fide scientific, educational, or exhibitional purposes. In establishing this exception, the FDA determined that these situations will not present a significant public health hazard since the scope of the exception is limited to a specific segment of society consisting of experts in the field who are fully aware of the contamination problems associated with turtles and the precautions required to prevent such contamination (40 FR 22545; May 23, 1975). Further, 21 CFR 1240.62 does not prohibit adult hobbyists from owning or making an occasional sale to another hobbyist, as long as such sales are not so frequent as to make the seller a dealer. 21 CFR 1240.62(d)(2). Therefore, the fact that the keeping of turtles may be an adult hobby is not adequate grounds for amending the regulation as you propose since hobbyists already are excepted from the regulation. Finally, your petition presents no evidence regarding the content and the extent of educational efforts of these "turtle organizations," how many members of the general public have been exposed to these efforts, or how many members of the general public understand and are likely to follow the recommendations of these organizations.

3. Cost to Raise Rare Turtle Species

You assert that "[m]any rare species are being bred in captivity in this country and the distribution of these turtles to responsible individuals becomes quite a hardship because of the cost and time to raise them to four inches. Some species are adults at only 4 inches."

This argument does not provide sufficient justification for amending 21 CFR 1240.62. As discussed above, individuals and groups can sell, hold for sale, or distribute turtle eggs and turtles with a carapace length of less than four inches for bona fide scientific, educational, or exhibitional purposes. If one is raising rare turtle species and one has a bona fide scientific, educational, or exhibitional purpose for selling, holding for sale, or distributing them, then the current regulation already exempts this conduct from the sale prohibition. In addition, the FDA has previously stated that the agency will consider petitions to amend the turtle sale prohibition to permit the sale of identified species, if it can be demonstrated that the species are so rare and expensive as to be of interest only to turtle hobbyists (40 FR 22545; May 23, 1975). However, your petition does not specify any particular turtle species nor present any evidence that such species are so rare and expensive as to be of interest only to turtle hobbyists.

4. Turtles In the Wild

Your petition states that "[m]any turtles are still being collected from the wild even though they could easily be bred in captivity. The legal sale of captive-bred turtles could reduce the numbers of those that come from the wild."

This argument does not provide sufficient justification for amending 21 CFR 1240.62. This ground is unclear and can be subject to two interpretations. If you are asserting that

your proposed amendment would reduce the number of turtles collected from the wild and that this has ecological or other value, then this ground is irrelevant. As discussed above, this regulation was implemented to prevent turtle-related human cases of salmonellosis. In the alternative, to the extent that you are suggesting that your proposed amendment would reduce the number of wild turtles in commerce and that this has a public health benefit, your petition contains no evidence that captive-bred turtles do not carry Salmonella. In fact, all turtles (whether captive-bred or wild) may carry Salmonella bacteria and thus pose a threat to human health. Section 1240.62 reduces the risk of salmonellosis by restricting the sale or distribution of these turtles and turtle eggs.

5. Health and Survival Rate of Captive Turtles

You assert that "[i]n most cases captive produced turtles are healthier and their survival rate in captivity is much greater than that of wild caught turtles."

This argument does not provide sufficient justification for amending 21 CFR 1240.62. First, it is not clear whether you are asserting that captive-bred turtles are "healthier" than wild turtles in the sense that they do not carry Salmonella. If so, you have provided no data or other evidence to support this assumption. If instead you are asserting that captive-bred turtles are "healthier" since they are more likely to be free of infirmity and disease than wild turtles, then this ground is irrelevant. As discussed above, this regulation protects the public health and prevents cases of salmonellosis in humans.

6. Posting of Notices of Sanitary Measures

Your petition states that "[t]he posting of notices would help discourage the sale of any size of turtle to children and would help educate potential buyers of the concern of Salmonella."

Your proposal to provide an information sheet to the purchaser describing the risks of keeping turtles and sanitary measures to reduce the risk of contracting salmonellosis does not adequately address the risk of salmonellosis. First, it is not clear what you mean by the phrase "highest sanitary measures." You present no evidence to support your assertion that posting notices will reduce cases of salmonellosis. For example, you provide no information to show that consumers would understand these sanitary measures, or that they would consistently follow them. Prior to the 1975 ban, it was suggested that warning legends be provided at the point of purchase or accompanying the purchase to warn the consumer of Salmonella. The warning legends were considered meaningless and ineffective (37 FR 24671; November 18, 1972). "...[S]mall children, for whom most pet turtles are purchased, cannot be expected to understand the reasons for, or abide by, sanitary measures that might protect them from illness" (40 FR 22544; May 23, 1975). Although more than twenty-five years has elapsed since the 1975 final rule was published, the level of children's maturity and understanding has remained constant in that children who may come into contact with turtles will not be able to appreciate the risks of contracting salmonellosis or to act in response to these risks.

7. Conservation Efforts by Private Breeders and Animal Dealers

Your petition states that "[t]his amendment would greatly benefit the conservation efforts made by private breeders, and animal dealers who are not affiliated with Zoos or Universities."

This argument does not provide sufficient justification for amending 21 CFR 1240.62. Although it is not clear how you define "private breeders" and "animal dealers," they

already may be excepted from the regulation's sale prohibitions if the turtles are used for bona fide scientific, educational, or exhibitional purposes. If you are asserting that better turtle conservation efforts would result from your proposed amendment, then this ground is irrelevant. Although conservation efforts are important, "[t]he sole objective of this regulation is to protect the public, primarily children, from contaminated pet turtles" (40 FR 22544; May 23, 1975).

8. Use of "Routine" Sanitary Measures

In your follow-up letter of August 1999 you state: "I believe if people use routine sanitation measures when handling turtles that the risk of contracting Salmonella is minimal if not non-existent."

This statement does not provide sufficient justification for amending 21 CFR 1240.62. First, it is not clear what you mean by "routine sanitation measures." Furthermore, as discussed above, turtles have historically been purchased by many adults as pets for children. Even if a turtle is purchased solely as a pet for an adult, if a child is present in the home, he/she may come into contact with a contaminated turtle or turtle environment. Children cannot be expected to understand and follow all necessary sanitary measures that would prevent salmonellosis. The FDA believes that a ban is the only effective method that will significantly reduce the possibility of human illness due to contaminated turtles.

9. Comparative Risk of Turtle Ownership

In your follow-up letter of August 1999, you state: "I do know that adults have been allowed to make the decision to smoke, drink, drive cars, sky dive, make home made eggnog, eat cookie dough, stuff turkeys with dressing, etc. Most of these pose a much greater danger than (after being educated about the risk of Salmonella) owning a turtle less than four inches."

The issue is not about such personal decisions as smoking, drinking, or driving cars, but is about addressing a large public health problem (280,000 cases/year of turtle-associated salmonellosis prior to 1975) which also has a particular significant impact on children as a high risk group, and of protecting those children who do not understand the risk of handling turtles or are unable to act in response to the risk. As discussed above, only a ban on the sale and distribution of these turtles can significantly reduce the risk of illness due to Salmonella-contaminated turtles.

10. Freedom of Choice

In your follow-up letter of August 1999, you state: "I don't think a whole lot of research is needed for the FDA to decide if informed adults should be allowed this freedom of chose [sic]. I do believe that the rights and freedoms of the people must be considered and kept in the equation!"

This statement does not provide sufficient justification for amending 21 CFR 1240.62. An "individual's right to purchase turtles must be measured against the known hazard to the health and welfare of the public as a result of their being offered for sale" (40 FR 22544; May 23, 1975). The Commissioner and the FDA's National Food and Drug Committee in 1975 fully explored and weighed the risk/benefit considerations of a ban on turtle sales before imposing the ban. Your petition has provided no new evidence that warrants an amendment of this ban.

B. Proposed 21 CFR 1240.62(d)(6)

Your follow-up letter of August 1999 requests that 21 CFR 1240.62 be amended as follows:

§ 1240.62(d)(6). The sale, holding for sale and distribution of live turtles under four inches, of the species *Trachemys scripta elegans*, red-eared sliders that have proven to be free of Salmonella. [And other requirements as agreed on by the FDA and Louisiana turtle breeders].

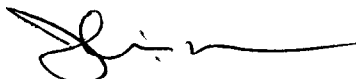
Your proposed 21 CFR 1240.62(d)(6) exception addresses the sale of red-eared slider turtles proven to be Salmonella-free. You seem to imply that, once the turtle eggs hatch and/or the turtles are free of Salmonella, that they will always be free of the organism. However, you present no evidence to support this assertion. In fact, to date, there has been no acceptable evidence presented for a scientific method that would result in Salmonella-free turtles. If you are aware of any such evidence, we invite you to submit this information for the FDA's review. Turtles often are asymptomatic carriers of Salmonella, with fecal carriage rates of up to 90%. Attempts to eliminate Salmonella from reptiles with antibiotics have been unsuccessful and have led to increased antibiotic resistance.⁸ The presence of such multi-drug resistant Salmonellae would be a problem in treating salmonellosis in humans.⁹ Therefore, this ground does not provide sufficient support for your proposed amendment.

III. Conclusion

In conclusion, for the reasons discussed above, we decline to amend the regulation as you petitioned. You have not demonstrated that your proposed amendment would provide sufficient safeguards to prevent turtle-related salmonellosis that can adversely affect children, the immuno-compromised, and the elderly. You have provided no evidence, nor is the FDA aware of any evidence, that demonstrates that turtles can be maintained Salmonella-free. Finally, you have not demonstrated with evidence that supplying information on the hazards of handling turtles, at the time of purchase or accompanying the purchase, would be sufficient to prevent the occurrence of salmonellosis, particularly in children, on a consistent basis throughout the life of the turtle.

Accordingly, the FDA is denying your petition.

Sincerely yours,



John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

Enclosures

⁸Centers for Disease Control, Reptile-Associated SalmonellosisB Selected States, 1994-95, Morbidity and Mortality Wkly. Rep. 347 (1995).

⁹Trust, T.L., and Karen H. Bartlett, *Aquarium Pets as a Source of Anti-biotic Resistant Salmonellae*, Can.J.of Microbiol., Vol. 25, 1979, pp. 535-541.