

Richard Fife

(b) (6)

December 07, 2015

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Reference:

Docket Number FDA-2013-S-0610

Proposed Amendment to
Code of Federal Regulations
Title 21, Volume 8
Revised as of April 1, 2015
21CFR Sec.1240.62

Dear Dr. Stephen Ostroff, M.D., Acting Commissioner:

Per discussion with the Division of Dockets Management staff on November 10, 2015
Environmental and Economic impact statements are not required for petitions submitted under
21CFR Sec.1240.62

CITIZEN PETITION
December 07, 2015

ACTION REQUESTED:

I propose an amendment to **21CFR Sec.1240.62** (see exhibit 1) as allowed by Section (d) *Petitions* as follows: Amend section (c) *Exceptions*. **The provisions of this section are not applicable to:**

By adding the following two (2) exceptions:

(5) The sale, holding for sale, and distribution of live turtles and viable turtle eggs, which are sold for a retail value of \$75 or more (not to include any additional turtle related apparatuses, supplies, cages, food, or other turtle related paraphernalia). This dollar amount should be reviewed every 5 years or more often, as deemed necessary by the department in order to make adjustments for inflation using the US Department of Labor, Bureau of labor Statistics, Consumer Price Index.

(6) The sale, holding for sale, and distribution of live turtles and viable turtle eggs, which are listed by the International Union for Conservation of Nature and Natural Resources (IUCN) Red List as Extinct In Wild, Critically Endangered, Endangered, or Vulnerable (IUCN threatened categorizes). All such " turtles" must be held and/or distributed in compliance with all local, state, and Federal laws and must be clearly identified by the common and scientific name including Genus, Species, and Subspecies (if applicable).

STATEMENT OF GROUNDS:

These two exceptions are allowed by 40 FR 22545; May 23, 1975 and reaffirmed by John M. Taylor, III, Associate Commissioner for Regulatory Affairs, Department of Health & Human Resources, on May 29, 2003 in response to a petition (Docket No. 98P-0680/CP) which was submitted to the FDA. Mr. Taylor's response stated: "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 or expensive as to be of interest only to turtle hobbyist (40 FR 22545; May 23, 1975)".

I requests that the regulation be amended as allowed by "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 or expensive as to be of interest only to turtle hobbyist"

In addition to the proposed exceptions I also recommend that the FDA require that anyone distributing live turtles to include a copy of the FDA/CDC brochure: "Pet Turtles: A Source of Germs" available at: [Pet Turtles: A Source of Germs \(brochure\) \(PDF\)](#) to all who purchase live turtles.

I believe there are reasonable grounds for the proposed amendment, which include:

1. An Adult Hobby: The keeping and care of turtles has progressed to a much higher standard than in 1975 (when the regulation was first implemented) and are now not only kept as pets but are kept by serious adult hobbyists. There are approximately 198 turtle species or subspecies currently being kept by hobbyists (see exhibit 2). There is an abundance of information available for the husbandry of turtles including the sanitary measures necessary to reduce the risk of salmonella.

A Google Search for "Turtle Care" resulted in over 43 million hits including numerous YouTube videos, care sheets, e-books, books, magazines, newsletters, forums, and groups, etc. A search for "Salmonella and Turtles" resulted in 228,000 hits. A search for "turtle identification" resulted in 828,000 hits. And a search for "Turtle and Tortoise groups and organizations" resulted in 340,000 hits including clubs, organizations, newsletters, societies, blogs, Face Book Groups, dot-org groups and organizations, and internet Forums, etc.

2. Rare Species: In order to "demonstrated that the species are so rare or expensive as to be of interest only to turtle hobbyist" the IUCN Red List was consulted and compared to the species kept by hobbyists. A list of turtle species kept by turtle hobbyists and serious collectors was provided by the "Turtle and Tortoise Preservations Group" (See exhibit 2), which indicates there are approximately 198 species and/or subspecies of turtles kept and bred by hobbyists in the USA.

The IUCN Red List, includes 131 of these 198 species or subspecies as of "Least Concern", "Near Threatened", or "Not Evaluated". However the IUCN Red list includes 67 of these species or subspecies (kept by hobbyists) as "Vulnerable", "Endangered", or "Critically Endangered". This is in stark contrast to the handful of turtle species sold as pets in 1975, with the red-ear slider being the prominent species bred in captivity.

My proposal would include all species or subspecies of turtles, which are listed by the IUCN as Vulnerable, Endangered, Critically Endangered, or Extinct in Wild to be included under (c) *exception*, and not applicable to the prohibition of turtles less than 4-inches.

3. Expensive Species: The original regulation was implemented to protect small children from contracting Salmonella. It was determined, by the FDA that a turtle over 4-inches would not be appealing as a child's pet, and a child would not be likely to put a turtle, over 4-inches into his or her mouth. In February 04, 2013 the CDC published a graph (see exhibit 3), which very vividly portrayed the risk of salmonella in children who were less than 5-years old. My research used this age group, as the age group most at risk, and for which a parent should not buy a pet turtle.

In order to "demonstrated that the species are so rare or expensive as to be of interest only to turtle hobbyist" an independent national survey company was hired to complete an impartial survey to help determine the highest dollar amount a parent would spend on a turtle for a small child (data collected by SurveyMonkey© see exhibit 4). The result of the survey show that 99% of those surveyed would pay less than \$75 for a turtle for small children. Therefore the amount of \$75 or more was proposed as the amount to be "so expensive as to be of interest only to turtle hobbyist" and included under (c) *exception*, and not applicable to the prohibition of turtles less than 4-inches.

4. Education: Education is always a front runner used to enforce measures to help protect our health. The FDA/CDC has already produced an excellent brochure "Pet Turtles: A Source of Germs" (see exhibit 5), which can be easily downloaded and printed by those who distribute turtles and can be provided as an excellent reminder to everyone who keep turtles.

CERTIFICATION:

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



signature

Richard John Fife

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