4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1240

[Docket No. FDA-2013-N-0639]

Turtles Intrastate and Interstate Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding the prohibition on the sale, or other commercial or public distribution, of viable turtle eggs and live turtles with a carapace length of less than 4 inches to remove procedures for destruction as FDA believes it is not necessary to routinely demand this destruction to achieve the purpose of the regulations. This action would reduce the need for investigator training and the time for the care and humane destruction of these animals.

DATES: Submit either electronic or written comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. If FDA receives any significant adverse comments, the Agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-0639, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (For paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2013-N-0639 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional instructions 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.regulations.gov 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: Dillard Woody, Center for Veterinary Medicine (HFV-231), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9237, email: dillard.woody@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA published regulations in § 1240.62 (21 CFR 1240.62) on May 23, 1975 (40 FR 22543), that ban the sale and distribution of viable turtle eggs and turtles with a carapace length

of less than 4 inches to stop the spread of turtle-associated salmonellosis in humans, especially in young children.

The regulations provide that viable turtle eggs and live turtles with a carapace length of less than 4 inches shall not be sold, held for sale, or offered for any other type of commercial or public distribution. The ban does not apply to such distribution for bona fide scientific, educational, or exhibitional purposes other than use as pets; to such distribution not in connection with a business; and to such distribution intended for export only. In addition, the turtle ban does not apply to marine turtles and their eggs.

The regulations further provide that any turtle eggs or live turtles with a carapace length of less than 4 inches that are held for sale or offered for any other type of commercial or public distribution in violation of the regulations shall be subject to destruction in a humane manner by or under the supervision of an officer or employee of FDA, in accordance with specified procedures. Once a written demand for destruction is served, the rule prohibits the selling, distributing, or otherwise disposing of the viable turtle eggs or live turtles in a manner other than destroying them under FDA supervision.

FDA is proposing to amend the regulations to remove the provisions making violative turtle eggs and live turtles routinely subject to destruction by or under the supervision of an officer or employee of FDA. FDA does not believe that it is necessary to routinely demand destruction of viable turtle eggs and live turtles with a carapace length of less than 4 inches. FDA believes that other activities would achieve the purpose of the regulations, which were enacted to prevent the spread of turtle-associated salmonellosis, especially to young children. These other alternatives include: Raising the turtles until the turtles achieve a carapace length of 4 inches or greater; donating the viable turtle eggs or live turtles to an entity that meets one of the

bona fide scientific, educational, or exhibitional exemptions, as provided in the regulations; or exporting the turtles in compliance with all applicable laws.

Although FDA does not believe it is necessary to routinely demand destruction of viable turtle eggs and live turtles with a carapace length of less than 4 inches, as provided for in the regulations, FDA recognizes that it has the authority and obligation to take appropriate measures to prevent the spread of communicable disease, especially in the face of widespread outbreaks or other public health emergencies. FDA would retain the authority to destroy or order the destruction of viable turtle eggs or live turtles of any size under 21 CFR 1240.30, which provides that, "[w]henever the Commissioner of Food and Drugs determines that the measures taken by health authorities of any State or possession (including political subdivision thereof) are insufficient to prevent the spread of any of the communicable diseases…he may take such measures to prevent such spread of the diseases as he deems reasonably necessary, including…destruction of animals or articles believed to be sources of infection."

This proposed rule would not affect the ban on the sale of viable turtle eggs and live turtles with a carapace length of less than 4 inches. Those provisions of the regulations would remain in effect. Violators would still be subject to a fine of not more than $1,000 or imprisonment for not more than 1 year, or both, for each violation, in accordance with section 368 of the Public Health Service Act (the PHS Act) (42 U.S.C. 271).

II. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published elsewhere in this issue of the Federal Register. FDA proposes to amend § 1240.62 by removing the provisions making viable turtle eggs and live turtles with a carapace length of less than 4 inches that are held for sale or offered for any other type of commercial or public distribution in violation of the

regulations routinely subject to destruction and the associated required procedures. This proposed rule is intended to make noncontroversial changes to existing regulations. The Agency does not anticipate receiving any significant adverse comment on this rule.

Consistent with FDA's procedures on direct final rulemaking, we are publishing elsewhere in this issue of the Federal Register a companion direct final rule. The direct final rule and this companion proposed rule are substantively identical. This companion proposed rule provides the procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for this proposed rule runs concurrently with the comment period of the companion direct final rule. Any comments received in response to the companion direct final rule will also be considered as comments regarding this proposed rule.

FDA is providing a comment period for the proposed rule of 75 days after the date of publication in the Federal Register. If FDA receives a significant adverse comment, we intend to withdraw the direct final rule before its effective date by publication of a notice in the Federal Register within 30 days after the comment period ends. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rule, the Agency will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553).

Comments that are frivolous, insubstantial, or outside the scope of the proposed rule will not be considered significant or adverse under this procedure. For example, a comment

recommending a regulation change in addition to those in the proposed rule would not be considered a significant adverse comment unless the comment states why the proposed rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this proposed rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the proposed rule that are not the subject of a significant adverse comment.

If FDA does not receive significant adverse comment in response to the proposed rule, the Agency will publish a document in the Federal Register confirming the effective date of the final rule. The Agency intends to make the direct final rule effective 30 days after publication of the confirmation document in the Federal Register.

A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the Federal Register of November 21, 1997 (62 FR 62466). The guidance document may be accessed at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm.

III. Legal Authority

FDA is issuing this proposed rule under the public health provisions of the PHS Act. Section 361 of the PHS Act (42 U.S.C. 264) allows the Secretary of the Department of Health and Human Services to make and enforce regulations that are necessary "to prevent the introduction, transmission, or spread of communicable diseases."

IV. Environmental Impact

FDA has determined under 21 CFR 25.32(g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Preliminary Regulatory Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposed rule would not affect the ban on the sale of viable turtle eggs and live turtles with a carapace length of less than 4 inches. Since it would allow for, but not require, a change in the disposition of any seized turtles or eggs, it would not impose any additional compliance costs. Further, it could result in a small savings to the Agency from reduced investigator training for the care and humane destruction of these animals. The Agency proposes to certify that the proposed rule if finalized would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price

Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

List of Subjects in 21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

Therefore under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1240 be amended as follows:

PART 1240--CONTROL OF COMMUNICABLE DISEASES

1. The authority citation for 21 CFR part 1240 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 264, 271.

§ 1240.62 [Amended]

2. In § 1240.62, remove paragraph (c) and redesignate paragraphs (d) and (e) as paragraphs (c) and (d), respectively.

Dated: July 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-17752 Filed 07/24/2013 at 8:45 am; Publication Date: 07/25/2013]