

DEPARTMENT OF FOOD AND AGRICULTURE

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August 14, 2000

FDA Dockets Management Branch
5630 Fishers Lane - Room 1061- HFA-305
Rockville, MD 20852

DOCKET NUMBER 00N-0504 - RE: COMMENTS ON "CURRENT THINKING PAPERS ON THE NATIONAL STANDARDS FOR EGG SAFETY"

The general principles represented in the Current Thinking Papers on the National Standards for Egg Safety are reflective of the core components currently in place with many of the existing egg quality assurance programs developed within individual states. It is appropriate that minimum national standards be established and that all producers of shell eggs implement a program to meet these standards. It is also the intent of FDA to contract with the states to implement the on-farm standards.

We recommend that FDA consider approving existing state programs that meet the minimum standards required in the federal regulation. In many cases, state programs are working very effectively and have standards higher than those being considered in the proposed regulation. This would minimize disruption of existing programs and sends a message in many cases that a "lesser standard" is acceptable. For example, a rigorous educational program is required to participate in the California Egg Quality Assurance Plan, followed by a written, detailed flock plan. Since we believe that we have one of the best educational programs in the country, we would like to ensure that it continues, rather than be replaced by something less that simply meets minimum standards.

In most cases, existing state programs could be modified very easily to meet all of the requirements of the federal regulation. The Food and Drug Administration (FDA) could review and certify those programs, and the state would be responsible to FDA to report producers in compliance with the state program. Those producers not currently participating in an approved program could elect to join the state program or simply meet the federal standards as required. It is likely that the cost for the state to administer its existing program, and report compliance to FDA, would be less than implementing an entirely "new federal program". While contract costs between states and FDA need to be negotiated, linking in to an existing approved program makes much more sense than developing and implementing an entirely new program.

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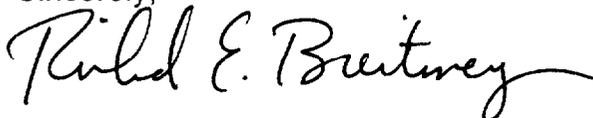
August 14, 2000

We also recommend that FDA reconsider its environmental sampling plan to include more appropriate risk analysis. It is very important that every premises producing shell eggs be monitored for *Salmonella* Enteritidis (SE) and take appropriate action if the premises if positive. Because of the ecology of SE and its ability to reside in rodents and survive in the environment, a positive premise is at higher risk than premises never found to be positive. Yet, the current FDA proposal calls for all premises to be monitored identically.

We recommend that each flock be required to be sampled at the end of the life of the flock. This first round of testing, when completed nation-wide, will identify those premises at higher risk of producing eggs contaminated with SE. Once identified, they can be evaluated, and if necessary, additional sampling of subsequent flocks on those premises can be implemented, to include egg diversion if necessary, based on risk analysis. We have submitted a specific risk-based proposal in previous comments.

Thank you for considering these additional comments. Please contact me if I can provide additional information.

Sincerely,

A handwritten signature in black ink that reads "Richard E. Breitmeyer". The signature is written in a cursive style with a long, sweeping underline.

Richard E. Breitmeyer, DVM, MPVM
State Veterinarian and Director
Animal Health and Food Safety Services

SUMMARY: The Food and Drug Administration (FDA) is publishing a notice announcing that it has received a petition requesting exemption from the premarket notification requirements for the total triiodothyronine test system class II device (special controls). FDA is publishing this notice in order to obtain comments on this petition in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments by August 10, 2000.

ADDRESSES: Submit written comments on this notice to the Docket Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94-295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Public Law 101-629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section

513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105-115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of the FDAMA, to publish in the *Federal Register* a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the *Federal Register*. FDA published that list in the *Federal Register* of January 21, 1998 (63 FR 3142). In the *Federal Register* of November 3, 1998 (63 FR 59222), FDA published a final rule codifying these exemptions.

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the *Federal Register* a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the *Federal Register* its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and

effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff." That guidance can be obtained through the Internet on the CDRH home page at <http://www.fda.gov/cdrh> or by facsimile through CDRH Facts-on-Demand at 1-800-899-0381 or 301-827-0111. Specify "159" when prompted for the document shelf number.

III. Petition

FDA received the following petition requesting an exemption from premarket notification for class II devices:

Abbott Laboratories, *Total triiodothyronine test system*, 21 CFR 862.1710.

IV. Comments

Interested persons may submit to the Docket Management Branch (address above) written comments regarding this petition by August 10, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 28, 2000.

Linda S. Kahan,
Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00-17389 Filed 7-10-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00N-0504]

Egg Safety; Current Thinking Papers on Egg Safety National Standards; Notice of Availability; Public Meeting

[Docket No. 98-045N4]

AGENCIES: Food and Drug Administration, HHS; Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) and the Food

notice and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/ stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office at 202-720-5704.

V. Public Dockets and Submission of Comments

The agencies have established public dockets to which comments may be submitted. Comments should be directed either to FSIS, Docket No. 98-045N4, or to FDA, Docket No. 00N-0504, or to both dockets for consideration by both agencies. All comments must include the appropriate docket number found in brackets in the heading of this document. Submit written comments in triplicate to: (1) USDA/FSIS Docket Clerk, 300 12th St. SW., rm. 102, Cotton Annex, Washington, DC 20250-3700, or (2) FDA's Dockets Management Branch (address above). You may also send comments to Dockets Management Branch at the following e-mail address: FDADockets@oc.fda.gov or via the FDA Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>.

VI. Meeting Summary

A summary of the proceedings of the public meeting will be posted on the Internet at www.foodsafety.gov. This website is a joint FDA, USDA, and Environmental Protection Agency food safety home page. It is linked to each agency for persons seeking additional food safety information. A summary of the proceedings of the public meeting may also be requested in writing from FDA's Dockets Management Branch (address above) approximately 30 business days after the meeting, at a cost of 10 cents per page. The summary of

the public meeting will be available for public examination at FDA's Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 5, 2000.

Thomas J. Billy,
Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture.

William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation, Food and Drug Administration.

[FR Doc. 00-17494 Filed 7-10-00; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-730 & 182]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection;

Title of Information Collection: Employee Building Pass Application and File;

Form No.: HCFA-730 & 182 (OMB# 0938-NEW);

Use: The purpose of this system and the forms are to control United States Government Building Passes issued to all HCFA employees and non-HCFA employees who require continuous access to HCFA buildings in Baltimore and other HCFA and HHS buildings;

Frequency: Other; as needed;

Affected Public: Federal Government, and Business or other for-profit;
Number of Respondents: 150;
Total Annual Responses: 150;
Total Annual Hours: 37.50.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: June 28, 2000.

John P. Burke III,
HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00-17477 Filed 7-10-00; 8:45 am]
BILLING CODE 4120-03-P

DEPARTMENT OF THE INTERIOR

Fish And Wildlife Service

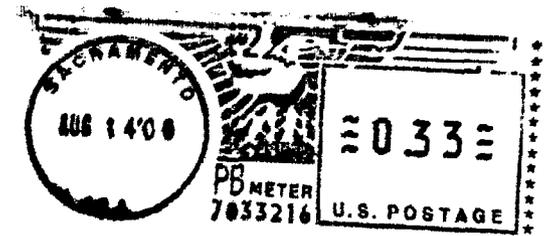
Endangered and Threatened Species: Incidental Take Permits—Houston Toad

Notice of Availability of an Environmental Assessment/Habitat Conservation Plan and Receipt of an Application for a Permit for the Incidental Take of the Houston toad (*Bufo houstonensis*) During Construction of One Single Family Residence on 0.5 acres of the 5.087-Acre Lot 41, Section 1 in the KC Estates Subdivision, Bastrop County, Texas (Bush).

SUMMARY: Anthony V. Bush (Applicant) has applied to the U.S. Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(a) of the Endangered Species Act (Act). The Applicant has been assigned permit number TE-029602-0. The requested permit, which is for a period of 5 years, would authorize the incidental take of the endangered Houston toad (*Bufo houstonensis*). The proposed take would occur as a result

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