

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98N-1230, 96P-0418, and 97P-0197]

DMB

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Certifier	<i>R. DeLorenzo</i>

Small Entity Compliance Guide: "Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule that published in the **Federal Register** of December 5, 2000 (65 FR 76092), entitled "Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution." The SECG is intended to set forth the requirements of that final rule in plain language and to help small businesses understand the regulation.

DATES: Submit written or electronic comments on this SECG at any time.

ADDRESSES: Submit written comments concerning this SECG to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single copies of the SECG to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St., Washington, DC 20204, 202-205-4561. Send one self-adhesive address label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT:

For the labeling provisions: Geraldine A. June, Center for Food Safety and Applied Nutrition

(HFS-822), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4168.

For refrigeration provisions: Nancy S. Bufano, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-401-2022.

SUPPLEMENTARY INFORMATION:

I. Background

To reduce the risk of illness and death from consumption of eggs contaminated with *Salmonella enteritidis* (SE), FDA published in the **Federal Register** of July 6, 1999 (64 FR 36492), a proposed rule requiring the labeling of shell eggs with a safe handling statement and the refrigeration of shell eggs at retail. FDA published the final rule in the **Federal Register** of December 5, 2000 (65 FR 76092).

FDA examined the economic implications of that final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-602) and determined that the final rule would have a significant economic impact on a substantial number of small entities.

In compliance with section 212 of the Small Business Regulatory Fairness Act (Public Law 104-121), FDA made available (via the Internet) a SECG stating in plain language the requirements of this regulation.

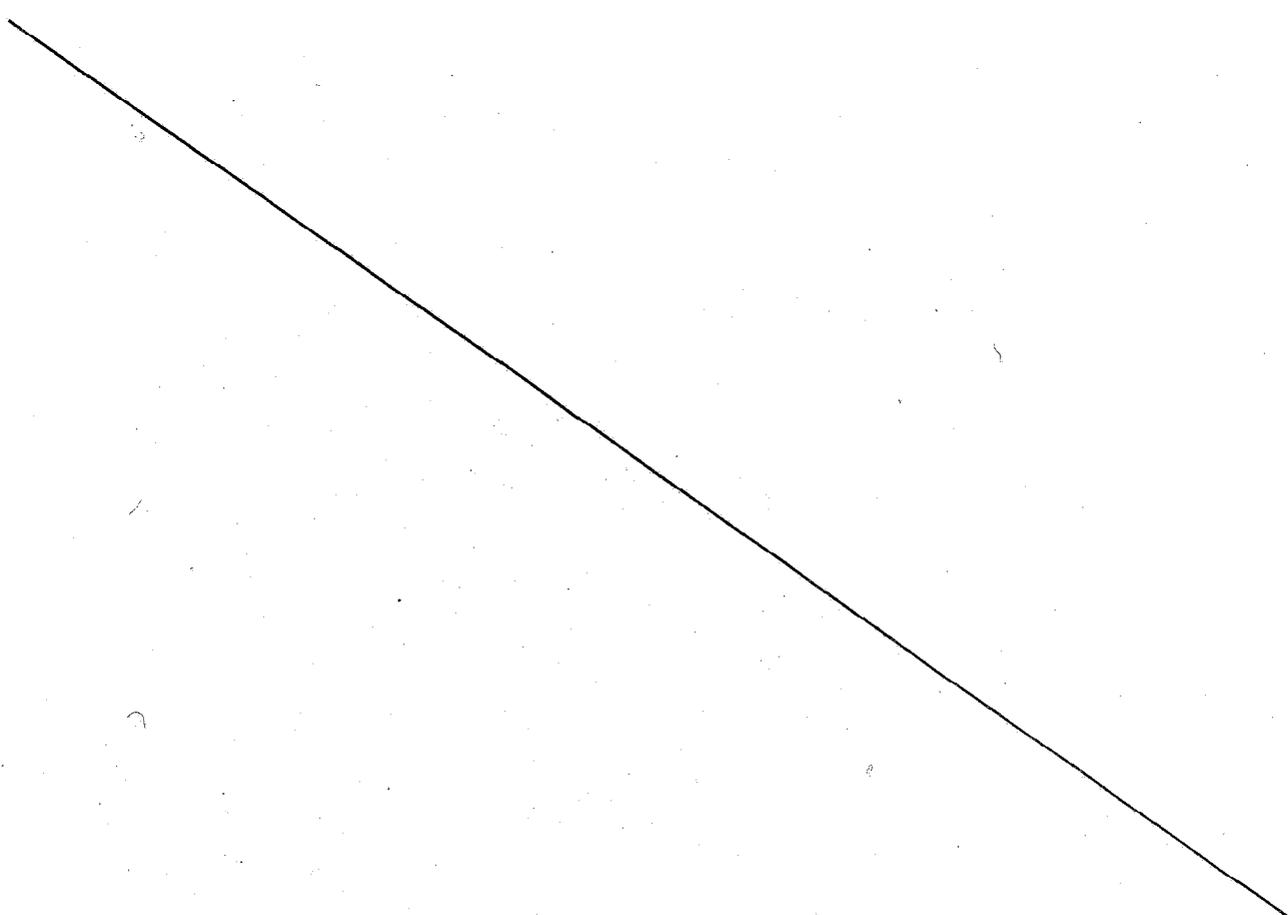
FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the SECG entitled "Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution" to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

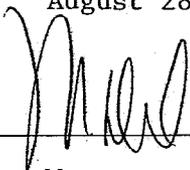
III. Electronic Access

Copies of the SECG may also be viewed on a personal computer with access to the Internet. Center for Food Safety and Applied Nutrition's home page includes the SECG and can be found at <http://www.cfsan.fda.gov/~dms/eggsguid.html>.



Dated: 8/28/01

August 28, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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