

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0184]

NMB

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Certifier	SR

**Compliance Policy Guide: "Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens;" Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) entitled "Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens." This CPG is intended to set forth FDA's internal enforcement priorities concerning undeclared food allergens.

**DATES:** Submit written comments on this CPG at any time.

**ADDRESSES:** Submit written requests for single copies of the CPG entitled "Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens" to the Director, Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-827-0482. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit written comments on the CPG to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

*Technical questions concerning allergens in foods:* Kathy Gombas, Office of Field Programs (HFS-615), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4231, FAX 202-260-0136.

*Questions concerning regulatory actions:* MaryLynn Datoc, Office of Enforcement (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0413, FAX 301-827-0482.

**SUPPLEMENTARY INFORMATION:**

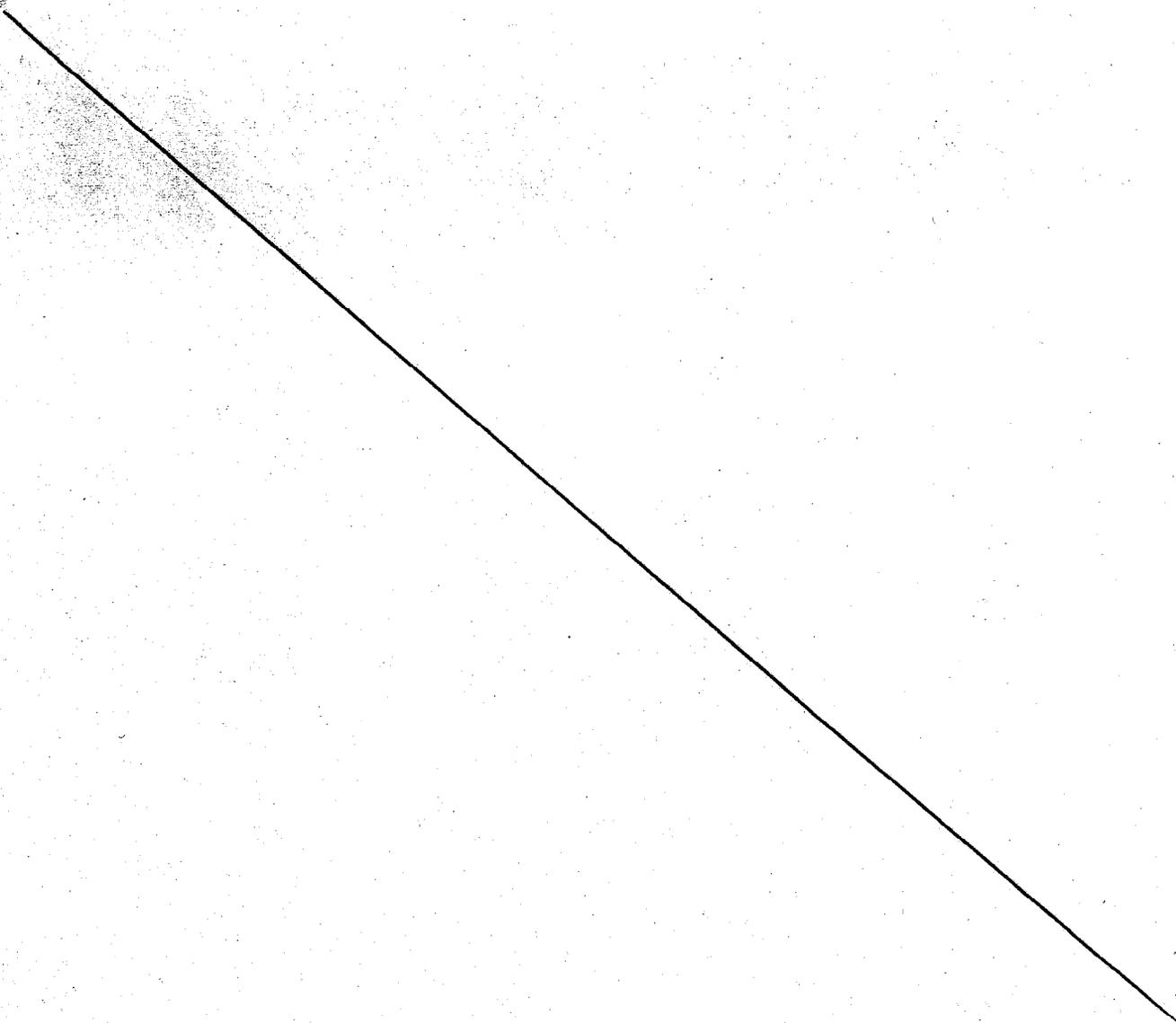
**I. Background**

FDA has developed a CPG on FDA's internal enforcement process concerning undeclared allergens in foods. The purpose of this CPG is to provide clear policy and regulatory guidance to FDA's field and headquarters staff. It also contains information that may be useful to the regulated industry and to the public. FDA is issuing this CPG as Level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance 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. The guidance is intended to further FDA's efforts to prevent potential serious allergic reactions in sensitive individuals resulting from undeclared allergens in foods. FDA is making this guidance document effective immediately because public participation prior to its implementation is not appropriate in these circumstances (21 CFR 10.115(g)(2); 65 FR 56478). Although the guidance document announced in this notice is being implemented immediately, FDA is requesting comments on the guidance. FDA will review all comments received, revise the guidance in response to the comments as appropriate, and publish a notice of availability if the guidance is revised.

**II. Comments**

Interested persons may, at any time, submit written comments on the CPG entitled "Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens," to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except

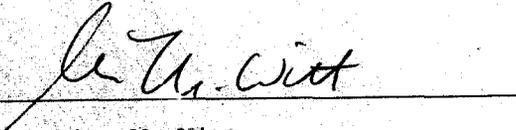
that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the CPG and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



### III. Electronic Access

Copies of the CPG may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs (ORA) home page includes the CPG and may be accessed at <http://www.fda.gov/ora> under "Compliance References."

Dated: April 27, 2001  
April 27, 2001.



Ann M. Witt,  
Acting Associate Commissioner for Policy.

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

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