

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1305]

DMB

Display Date	<u>10-30-01</u>
Publication Date	<u>10-31-01</u>
Certifier	<u>A. DeLeon</u>

Compliance Policy Guide: “Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration with Patulin,” Availability; and “Patulin in Apple Juice, Apple Juice Concentrates and Apple Juice Products,” Supporting Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) entitled “Apple Juice, Apple Juice Concentrates, and Apple Juice Products-Adulteration with Patulin.” This document is intended to make FDA offices and the industry aware of FDA’s guidance for enforcement concerning apple juice, apple juice concentrates, and apple juice products that contain patulin, a toxic substance produced by molds that may grow on apples and that has been found to occur at high levels in some apple juice products offered for sale in the United States. The agency also is announcing the availability of a document entitled “Patulin in Apple Juice, Apple Juice Concentrates and Apple Juice Products” (final supporting document).

DATES: Submit written or electronic comments on the CPG or the final supporting document at any time.

ADDRESSES: Submit written requests for single copies of the CPG entitled “Apple Juice, Apple Juice Concentrates, and Apple Juice Containing Products—Adulteration with Patulin” and/or the final supporting document entitled “Patulin in Apple Juice, Apple Juice Concentrates and Apple Juice Products” to the Office of Plant and Dairy Foods and Beverages (HFS-305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, cf0145

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Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send two self-addressed adhesive labels to assist that office in processing your request. Submit written comments to the Docket 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these documents.

FOR FURTHER INFORMATION CONTACT:

Technical questions concerning patulin in apple juice products: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5321, FAX 202-205-4422, e-mail: mkashtoc@cfsan.fda.gov.

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, e-mail: mdatoc@ora.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of June 16, 2000 (65 FR 37791), FDA announced the availability of a draft CPG entitled "Apple Juice, Apple Juice Concentrates, and Apple Juice Products-Adulteration with Patulin" and a draft supporting document entitled "Patulin in Apple Juice, Apple Juice Concentrates, and Apple Juice Products." The agency has finalized the draft, CPG and the draft supporting document after considering the comments we received on these documents.

FDA received four comments on these two documents, three from food industry associations and one from an organization representing several foreign governments. Three of the comments supported the draft CPG and draft supporting document and did not raise any questions.

The fourth comment posed three questions about the action level and the safety assessment described in the draft supporting document. FDA has considered these questions and has responded to them in the revised supporting document.

II. Significance of Guidance

This CPG is being issued as guidance consistent with FDA's good guidance practices regulation in 21 CFR 10.115. The CPG represents the agency's current thinking on its enforcement process concerning the adulteration of apple juice, apple juice concentrates, and apple juice products with patulin. 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 statute and regulations.

III. Comments

Interested persons may, at any time, submit to the Docket Management Branch (address above) written or electronic comments concerning the CPG entitled "Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration with Patulin" or the final supporting document. 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. Comments also may be submitted electronically. A copy of the CPG and the final supporting 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.

IV. Electronic Access

Persons with access to the Internet may obtain the CPG at <http://www.fda.gov/ora> under "Compliance References." The supporting document may be accessed at <http://www.cfsan.fda.gov> under the heading "How to Obtain FDA Food & Cosmetic Guidance Documents."

Dated: 10/22/01
October 22, 2001.



Dennis E. Baker,
Associate Commissioner--for Regulatory Affairs.

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

BILLING CODE 4160-01-S

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