



COMPLIANCE POLICY GUIDE

Compliance Policy Guidance for FDA Staff

CHAPTER - 5

SUB CHAPTER – 510

Sec. 510.150 Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin

This guidance document 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.

INTRODUCTION

This compliance guidance document is an update to the Compliance Policy Guides Manual (August 2000 edition). It is a new CPG and will be included in the next printing of the Compliance Policy Guides Manual. It is intended for FDA personnel and is available electronically to the public.

BACKGROUND:

Patulin is a toxic substance produced by molds that may grow on apples. In the past, patulin has been found to occur at high levels in some apple juice products offered for sale in or import into the U.S.

REGULATORY ACTION GUIDANCE:

The following criteria should be considered in deciding whether to recommend legal action or whether to recommend detention of imports to CFSAN/Office of Field Programs/Division of Enforcement and Programs (HFS-605):

The sample is analyzed in accordance with applicable methods of the current Official Methods of Analysis of the Association of Official Analytical Chemists', and its supplements, and both of the following conditions are met:

¹ At the time of this issuance, the current method can be found in the Seventeenth Edition, section 995.10 - **Patulin** in apple juice, liquid chromatographic method, AOAC-IUPAC-IFJU Method. This method was adopted by AOAC International in 1995. The method was published in JAOAC 79(2):452-455, 1996.

GDL 2



1. Original and check analysis show patulin at or above 50 micrograms per kilogram (50 parts per billion) as determined on single strength apple juice, reconstituted single strength apple juice (if the food is an apple juice concentrate), or the single strength apple juice component of the food (if the food contains apple juice as an ingredient); (For the purpose of this guidance, single strength juice is 100 percent juice that is unconcentrated (see 21 CFR 101.30(h)).)

and

2. Identity of patulin is confirmed by gas chromatography/mass spectrometry.

SPECIMEN CHARGE:

For domestic goods:

The article (apple juice, apple juice concentrate, or apple juice product) was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce within the meaning of 21 U.S.C. 342 (a)(1), in that it bears or contains an added poisonous or deleterious substance, patulin, which may render the article of food injurious to health.

For imported goods:

The article (apple juice, apple juice concentrate, or apple juice product) is subject to refusal of admission pursuant to 21 U.S.C. 381 (a)(3) in that it appears to bear or contain an added poisonous or deleterious substance, patulin, which may render the article injurious to health (adulteration under 21 U.S.C. 342 (a)(1)).

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