

DDM

Display Date 3-28-08
Publication Date 3-31-08
Certifier A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0143] (formerly Docket No. 2006D-0056)

Compliance Policy Guide Sec. 500.500 Guidance Levels for 3-MCPD (3-chloro-1, 2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of compliance policy guide (CPG) Sec. 500.500 Guidance Levels for 3-MCPD (3-chloro-1, 2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces. The CPG provides regulatory action guidance for FDA staff regarding 3-MCPD in acid-hydrolyzed protein (acid-HP) and Asian-style sauces.

DATES: Submit written or electronic comments regarding the CPG at any time.

ADDRESSES: Submit written comments on the CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to: <http://www.regulations.gov>.

Submit written requests for single copies of CPG Sec. 500.500 Guidance Levels for 3-MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6860. Send two self-addressed adhesive labels to assist that

CF0754

FDA.2008.D.0143

NAD

office in processing your request, or fax your request to 240-632-6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

FOR FURTHER INFORMATION CONTACT: Judith L. Kidwell, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 20740-3835, 301-436-1071.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 23, 2006 (71 FR 29651), FDA announced the availability of draft CPG Sec. 500.500 Guidance Levels for 3-MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces. FDA received one comment on the draft CPG. The International Hydrolyzed Protein Council (IHPC) offered clarification for the following sentence found in the **BACKGROUND** section of the draft CPG: "Since 1996, many countries * * * have recommended or required that industry take steps to ensure that 3-MCPD is not detectable in acid-HP or Asian-style sauces at levels ranging from 0.01 parts per million (ppm) to 1 ppm." IHPC suggested that we revise the sentence as follows: "Since 1996, many countries * * * have recommended or required that industry take steps to ensure that 3-MCPD in acid-HP or Asian-style sauces does not exceed levels ranging from 0.01 parts per million (ppm) to 1 ppm." IHPC explained that using the phrase "not detectable" and then listing allowable levels is confusing. We concur with the comment and have revised the final CPG accordingly. FDA also revised the **SPECIMEN CHARGES** section in the final CPG to provide operational guidance regarding reference to the United States Code (U.S.C.) when citing the violation charged in a domestic seizure and reference to the Federal Food, Drug, and

Cosmetic Act when citing the violation charged in an import detention. We also have made other editorial changes to the CPG for clarification.

This CPG is being issued as level 1 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115). The CPG represents the agency's current thinking on 3-MCPD in acid-HP and Asian-style sauces. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the CPG at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

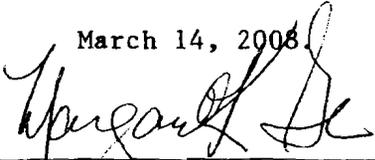
Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the CPG from the Office of Regulatory Affairs home page at <http://www.fda.gov/ora> under "Compliance Reference."

Dated: 3-14-2008

March 14, 2008



Margaret O'K. Glavin,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

