b. In the last sentence, by removing the words ''and Customs Form 7512–C (duplicate)''; and

c. By removing the second and third sentences.

3. Section 122.92 is amended by removing paragraph (a)(2) and redesignating paragraph (a)(3) as paragraph (a)(2).

4. Section 122.92(b)(1) is amended:

a. In the first sentence, by removing the words '', and the duplicate copy of Customs Form 7512–C''; and

b. By removing the last sentence.

5. Section 122.92(b)(2) is amended by removing the words ''one copy of Customs Form 7512–C or'' and adding, in their place, the word ''any''.

6. Section 122.93(a) is amended in the first sentence, by removing the words ''with Customs Form 7512–C attached''.

7. Section 122.94(a) is amended in the second sentence, by removing the words '', Customs Form 7512 with Customs Form 7512–C attached,'' and adding, in their place, the words ''and a Customs Form 7512''.

8. Section 122.119(c) is amended:

a. By removing in the introductory text, the words '', and two copies of Customs Form 7512–C (original and duplicate)'';

b. By adding a second sentence, at the end of the introductory text, as follows:

* * * * *

(c) * * * The permit copy is used and kept by Customs at the port of arrival.

* * * * *

c. By removing paragraphs (c)(1) and (2).

9. In § 122.120:

a. Paragraph (d) is amended in the introductory text, by removing the words ''and a Customs Form 7512–C (original and duplicate)'';

b. Paragraph (d)(1) is amended in the first sentence, by removing the words ''and Customs Form 7512–C (original)'' and by removing the second sentence; and

c. Paragraph (i) is amended by removing the words ''Forms 7512 and 7512–C'' and adding, in their place, the words ''Form 7512''.

## PART 123—CUSTOMS RELATIONS WITH CANADA AND MEXICO

1. The general authority citation for part 123 continues to read as follows:

**Authority:** 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1431, 1433, 1436, 1448, 1624.

* * * * *

2. Section 123.42(c)(1) is amended in the last sentence by removing the words ''with the related Customs Form 7512–C (destination)''.

3. Section 123.42(d) is amended in the first sentence by removing the words ''and the related Customs Form 7512–C (destination)''.

4. Section 123.64(b) is amended in the second sentence by removing the words ''and related Customs Form 7512–C (destination)''.

## PART 144—WAREHOUSE AND REWAREHOUSE ENTRIES AND WITHDRAWALS

1. The general authority citation for part 144 continues to read as follows:

**Authority:** 19 U.S.C. 66, 1484, 1557, 1559, 1624.

* * * * *

2. Section 144.37(a) is amended in the first sentence by removing the words '', accompanied by Customs Form 7512–C (Transportation Entry and Manifest of Goods)''.

## PART 146—FOREIGN TRADE ZONES

1. The authority citation for part 146 continues to read as follows:

**Authority:** 19 U.S.C. 66, 81a–81u, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1623, 1624.

2. Section 146.68(b) is amended:

a. In the fourth sentence by removing the words ''and the destination copy (Customs Form 7512–C)''; and

b. In the last sentence by removing the words ''and the origin copy (Customs Form 7512–C)''.

**Raymond W. Kelly,**

*Commissioner of Customs.*

Approved: January 24, 2000.

**John P. Simpson,**

*Deputy Assistant Secretary of the Treasury.*

[FR Doc. 00–7557 Filed 3–28–00; 8:45 am]

**BILLING CODE 4820–02–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 176

**[Docket No. 93F–0132]**

## Indirect Food Additives: Paper and Paperboard Components

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin as a preservative in clay-type fillers for paper and paperboard intended for use in contact with aqueous and fatty food. This action is in response to a petition filed by Lonza, Inc.

**DATES:** This rule is effective March 29, 2000. Submit written objections and requests for a hearing by April 28, 2000.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3094.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In a notice published in the **Federal Register** May 17, 1993 (58 FR 28882), FDA announced that a food additive petition (FAP 3B4367) had been filed by Lonza, Inc., c/o Delta Analytical Corp., 1414 Fenwick Lane, Silver Spring, MD 20910. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105), § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300), and § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of a mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin as a preservative in adhesives, resinous and polymeric coatings and clay-type fillers for paper and paperboard in food-contact articles. Lonza, Inc., is currently represented by Lewis and Harrison, 122 C St. NW., suite 740, Washington, DC 20001. (Formerly represented by Delta Analytical Corp. whose current address is 7910 Woodmont Ave., Bethesda, MD 20814).

When the petition was filed on May 17, 1993, the petitioner proposed to amend the food additive regulations in §§ 175.105, 175.300, and 176.170. Subsequent to the filing of the petition, the petitioner amended the petition to limit the use of the additive to the manufacture of paper and paperboard under § 176.170.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive, a mixture of

hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin as a preservative in clay-type fillers for paper and paperboard intended to contact aqueous and fatty food is safe; (2) the additive will achieve its intended technical effect; and therefore, (3) the regulation in § 176.170(a)(5) should be amended as set forth below.

FDA's review of the petition indicates that the additive may contain trace amounts of formaldehyde as an impurity. The potential carcinogenicity of formaldehyde was reviewed by the Cancer Assessment Committee (the Committee) of FDA's Center for Food Safety and Applied Nutrition. The Committee noted that for many years, formaldehyde has been known to be a carcinogen by the inhalation route, but the Committee concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The Committee's conclusion was based on the fact that the route of administration (inhalation) is not relevant to the safety of formaldehyde residues in food and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). In addition, the agency has received literature reports of two-year drinking-water studies on formaldehyde: (1) A preliminary report of a carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1); and (2) a negative study by Til et al. (1989), conducted in The Netherlands (Ref. 2). The Committee reviewed both studies and concluded, concerning the Soffritti study, ''* * * that data reported were unreliable and could not be used in the assessment of the oral carcinogenicity of formaldehyde'' (Ref. 3). This conclusion is based on a lack of critical detail in the study, questionable histopathological conclusions, and the use of unusual nomenclature to describe the tumors. Based on the Committee's evaluation, the agency has determined that there is no basis to conclude that formaldehyde is a carcinogen when ingested.

A mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin intended as a preservative in clay-type fillers for paper and paperboard intended in contact with aqueous and fatty foods is regulated under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) as a food additive and not as a pesticide chemical under section 408 of the act (21 U.S.C. 346a). However, this intended use of a mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to market food-contact articles containing a mixture of hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin for this intended use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## II. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by April 28, 2000. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Soffritti, M., C. Maltoni, F. Maffei, and R. Biagi, ''Formaldehyde: An Experimental Multipotential Carcinogen,'' *Toxicology and Industrial Health*, vol. 5, No. 5, pp. 699–730, 1989.

2. Til, H. P., R. A. Woutersen, V. J. Feron, V. H. M. Hollanders, H. E. Falke, and J. J. Clary, ''Two-Year Drinking-Water Study of Formaldehyde in Rats,'' *Food Chemical Toxicology*, vol. 27, No. 2, pp. 77–87, 1989.

3. Memorandum of Conferences concerning ''Formaldehyde,'' Meeting of the Cancer Assessment Committee, FDA, April 24, 1991, and March 4, 1993.

## List of Subjects in 21 CFR Part 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 176 is amended as follows:

## PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 346, 348, 379e.

2. Section 176.170 is amended in the table in paragraph (a)(5) by alphabetically adding an entry under the headings ''List of Substances'' and ''Limitations'' to read as follows:

### § 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(a) * * *

(5) * * *

| List of Substances | Limitations |
|---|---|
| * * * * * * * | |
| Hydroxymethyl-5,5-dimethylhydantoin (CAS Reg. No. 27636–82–4), mixture with 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin (CAS Reg. No. 6440–58–0). | For use only as a preservative in clay-type fillers at a level not to exceed a combined total of 1,200 milligrams/kilograms hydroxymethyl-5,5-dimethylhydantoin and 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin in the filler. |
| * * * * * * * | |

* * * * *

Dated: March 20, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00–7655 Filed 3–28–00; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 862

**[Docket No. 00P–0931]**

## Clinical Chemistry Devices; Classification of the Biotinidase Test System

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the biotinidase test system into class II (special controls). The special control that will apply to this device is restriction to sale, distribution, and use as a prescription device. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. The agency is classifying these devices into class II (special controls) in order to provide a reasonable assurance of the safety and effectiveness of the devices.

**DATES:** This rule is effective April 28, 2000.

**FOR FURTHER INFORMATION CONTACT:** Carol C. Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or class II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the FDA regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on November 19, 1999, classifying the Wallac Neonatal Biotinidase Test Kit in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On December 20, 1999, FDA filed a petition submitted by PerkinElmer requesting classification of the Wallac Neonatal Biotinidase Test Kit into class II under section 513(f)(2) of the act.

After review of the information submitted in the petition, FDA determined that the Wallac Neonatal Biotinidase Test Kit can be classified in class II with the establishment of special controls. This device is intended for use in the semiquantitative in vitro determination of biotinidase activity in blood specimens collected onto filter paper to screen newborns for biotinidase deficiency, an inborn error of metabolism. FDA believes that class II special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

In addition to the general controls of the act, Wallac Neonatal Biotinidase Test Kit is subject to the following special control: The sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 (21 CFR 801.109). Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. The test is widely used in newborn screening programs and FDA review of data sets and labeling ensure that minimum levels of performance are obtained before marketing and are subject to impartial external quality control before labeling is put into place. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the biotinidase test system before marketing the device.