consider any additional and cumulative effects of obesity.

5. Listing 3.00 in part A of appendix 1 is amended by removing the last sentence of paragraph H and adding new paragraph I. to read as follows:

3.00 Respiratory System

* * * * *

I. *Effects of obesity.* Obesity is a medically determinable impairment that is often associated with disturbance of the respiratory system, and disturbance of this system can be a major cause of disability in individuals with obesity. The combined effects of obesity with respiratory impairments can be greater than the effects of each of the impairments considered separately. Therefore, when determining whether an individual with obesity has a listing-level impairment or combination of impairments, and when assessing a claim at other steps of the sequential evaluation process, including when assessing an individual's residual functional capacity, adjudicators must consider any additional and cumulative effects of obesity.

6. Listing 3.10 in Part A of appendix 1 is revised to read as follows:

3.10 *Sleep-related breathing disorders.* Evaluate under 3.09 (chronic cor pulmonale) or 12.02 (organic mental disorders).

7. Listing 4.00 in Part A of appendix 1 is amended by adding new paragraph F. to read as follows:

4.00 Cardiovascular System

* * * * *

F. *Effects of obesity.* Obesity is a medically determinable impairment that is often associated with disturbance of the cardiovascular system, and disturbance of this system can be a major cause of disability in individuals with obesity. The combined effects of obesity with cardiovascular impairments can be greater than the effects of each of the impairments considered separately. Therefore, when determining whether an individual with obesity has a listing-level impairment or combination of impairments, and when assessing a claim at other steps of the sequential evaluation process, including when assessing an individual's residual functional capacity, adjudicators must consider any additional and cumulative effects of obesity.

8. Listing 9.00 in part A of appendix 1 is amended by removing ''AND OBESITY'' from the title and removing the last two paragraphs from the preface.

9. Listing 9.01 in part A of appendix 1 is amended by removing ''and Obesity'' from the title.

10. Listing 9.09 in part A of appendix 1 is removed.

[FR Doc. 99–21935 Filed 8–23–99; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 96F–0145]

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 tetrakis(hydroxymethyl)phosphonium sulfate (CAS Reg. No. 55566–30–8) as a slimicide for use in the manufacture of paper and paperboard that contact food. This action responds to a petition filed by Albright & Wilson, Ltd.

DATES: This regulation is effective August 24, 1999; submit written objections and requests for a hearing by September 23, 1999.

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:

In a notice published in the **Federal Register** of May 20, 1996 (61 FR 25228), FDA announced that a food additive petition (FAP 5B4472) had been filed by Albright & Wilson, Ltd., c/o Delta Analytical Corp., 7910 Woodmont Ave., suite 1000, Bethesda, MD 20814. The petition proposed to amend the food additive regulations in § 176.300 *Slimicides* (21 CFR 176.300) to provide for the safe use of tetrakis(hydroxymethyl)phosphonium sulfate as a slimicide in the manufacture of paper and paperboard intended to contact food. Albright and Wilson, Ltd. is currently represented by Lewis & Harrison, 122 C St. NW., suite 740, Washington, DC 20001. (Formerly represented by Delta Analytical Corp., 7910 Woodmont Ave., suite 1000, Bethesda, MD 20814.)

When the petition was filed on May 20, 1996, it contained an environmental assessment (EA). In the notice of filing, the agency announced that it was placing the EA on display at the Dockets Management Branch for public review and comment (61 FR 25228). No comments were received. On July 29, 1997 (62 FR 40569), FDA published revised regulations under part 25 (21 CFR part 25), which became effective on August 28, 1997. On January 7, 1999, the petitioner submitted a claim of categorical exclusion under new § 25.32(q), in accordance with the procedures in § 25.15(a) and (d). Because the agency had not completed its review of the earlier submitted EA, the agency reviewed the claim of categorical exclusion under § 25.32(q) for the final rule and has determined that this action is a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an EA nor an environmental impact statement is required.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of tetrakis(hydroxymethyl)phosphonium sulfate as a slimicide in the manufacture of paper and paperboard that contact food is safe; (2) the additive will achieve its intended technical effect; and therefore,(3) the regulation in § 176.300(c) should be amended as set forth below.

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.

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

Any person who will be adversely affected by this regulation may at any time on or before September 23, 1999, file with the Dockets Management Branch (address above) written objections thereto. 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 shall be submitted and shall 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.

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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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 176.300 is amended by alphabetically adding an entry to the table in paragraph (c) to read as follows:

§ 176.300 Slimicides.

* * * * *

(c) * * *

List of Substances	Limitations
* * * * * * *	
Tetrakis(hydroxymethyl)phosphonium sulfate (CAS Reg. No. 55566–30–8)	Maximum use level of 84 mg/kg in the pulp slurry. The additive may also be added to water, which when introduced into the pulp slurry, results in a concentration in the pulp slurry not to exceed 84 mg/kg.
* * * * * * *	

* * * * *

Dated: August 12, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–21851 Filed 8–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 98F–0871]

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 polyethylene glycol monoisotridecyl ether sulfate, sodium salt as a component of coatings on paper and paperboard intended for use in contact with dry food. This action is in response to a petition filed by Servo Deldon BV.

DATES: This regulation is effective August 24, 1999; submit written objections and requests for a hearing by September 23, 1999.

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: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 13, 1998, (63 FR 54717), FDA announced that a food additive petition (FAP 8B4630) had been filed by Servo Deldon BV, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) to provide for the safe use of polyethylene glycol monoisotridecyl ether sulfate, sodium salt as a component of coatings on paper and paperboard intended for use in contact with dry food.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of unreacted 1,4-dioxane and ethylene oxide, carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as 1,4-dioxane and ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the general safety standard of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as a '' reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additives anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).