additives are exempt from the certification requirements of section 721(c) of the act.

Dated: September 26, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–25261 Filed 10–2–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 95F–0175]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to expand the safe use of sodium 2,2′-methylenebis (4,6-di-*tert*-butylphenyl) phosphate as a clarifying agent in polypropylene articles intended for contact with food. This action is in response to a petition filed by Asahi Denka Kogyo K.K.

DATES: Effective October 3, 1996; written objections and requests for a hearing by November 4, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John R. Bryce, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3023.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 13, 1995 (60 FR 36149), FDA announced that a food additive petition (FAP 5B4458) had been filed by Asahi Denka Kogyo K.K., c/o Japan Technical Information Center, Inc., 775 South 23d St., Arlington, VA 22202. The petition proposed to amend § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) of the food additive regulations to provide for the safe use of sodium 2,2′-methylenebis (4,6-di-*tert*-butylphenyl) phosphate as a clarifying agent in polypropylene articles intended for contact with food under conditions of use A and B as described in Table 2 of 21 CFR 176.170(c).

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, and the additive will achieve its intended technical effect; therefore the regulations in § 178.3295 should be amended as set forth below.

FDA's review of the subject 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 it 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 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 the 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 histopathologic 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.

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.

Any person who will be adversely affected by this regulation may at any time on or before November 4, 1996, 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.

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. 5:699–730, 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 Conference concerning ''Formaldehyde,'' Meeting of the Cancer Assessment Committee, FDA, April 24, 1991, and March 4, 1993.

List of Subjects in 21 CFR Part 178

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 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.3295 is amended in the table by revising the entry for ''Sodium 2,2′-methylenebis (4,6-di-*tert*-butylphenyl) phosphate'' to read as follows:

§ 178.3295 Clarifying agents for polymers.

* * * * *

Substances	Limitations
* * *	* * * *
Sodium 2,2′-methylenebis (4,6-di-*tert*-butylphenyl) phosphate (CAS Reg. No. 85209–91–2).	For use only: 1. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from polypropylene). The finished polymers contact foods only of types I, II, IV-B, VI-B, VII-B, and VIII as identified in Table 1 of § 176.170(c) of this chapter and limited to conditions of use B through H, described in Table 2 of § 176.170(c), or foods of all types, limited to conditions of use C through H described in Table 2 of § 176.170(c). 2. As a clarifying agent at a level not exceeding 0.10 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, item 1.1. The finished polypropylene may be used in contact with foods of all types under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.

Dated: September 26, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–25258 Filed 10–2–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Oxytetracycline Type A Medicated Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides revised labeling for Pfizer's pioneer, Type A, oxytetracycline-containing, medicated articles which brings the products into compliance with the findings of the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group's (DESI) effectiveness evaluation and subsequent FDA conclusions. In addition, the regulations are further amended to reflect approval, based on FDA's DESI ''me-too'' policy, of one original NADA each filed by Pfizer and PennField Oil Co. for Type A medicated articles that are copies of the Pfizer pioneer products.

EFFECTIVE DATE: October 3, 1996.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to its approved NADA 8–804 which covers the Type A medicated articles bearing the Terramycin® (oxytetracycline (OTC)) trade name on their labels. The articles contain OTC quaternary salt expressed in terms of an equivalent amount of OTC hydrochloride (HCl) (i.e., Terramycin® 10, 20, 50, 50D, 100, 100D, 100SS, and 200). Pfizer also filed original NADA 95–143 which covers the Type A medicated articles OXTC® 10, 30, 50, 50–S, 100, 100–S, 100MR, and 200. These articles contain OTC dihydrate base expressed in terms of an equivalent amount of OTC HCl. PennField Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed original NADA 138–938 which covers the Type A medicated articles Oxytetracycline 50, 100, and 100 MR (formulated for use in calf milk replacers or starter feeds). These articles also contain OTC quaternary salt expressed in terms of an equivalent amount of OTC HCl.

Pfizer Type A medicated articles covered by NADA 8–804 were the subject of a NAS/NRC DESI evaluation of effectiveness (DESI 8622V). The findings were published in the Federal Register of May 5, 1970 (35 FR 7089). NAS/NRC evaluated the articles as probably effective when used for the control and treatment of specific diseases of livestock (swine, cattle, sheep, rabbits, and mink) and poultry (broiler chickens, laying chickens, and turkeys), and concluded that use may result in faster gains and improved feed efficiency under appropriate conditions. NAS/NRC stated that:

1. Labels and package inserts require extensive revision. There is inadequate documentation of claims, excessive claims are made, and bold conclusions are reached in the absence of sufficient controlled experimental evidence.

2. Claims for growth promotion or stimulation are not allowed and claims for faster gains and/or feed efficiency should be stated as ''may result in faster gains and/or improved feed efficiency under appropriate conditions.''

3. Each disease claim should be properly qualified as ''appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug) and if the disease cannot be so qualified the claim must be dropped.''

4. The label claims ''for prevention of'' or ''to prevent'' should be replaced with ''as an aid in the control of'' or ''to aid in the control of.''

5. The label claim pertaining to egg production and hatchability should be modified to read, ''May aid in maintaining egg production and