$27 million that NPA estimated. Such costs will surely be passed on to consumers.

Although NPA has demonstrated that significant problems will be presented by the transition to fortification of enriched grains with folic acid, it has not explained why the effective date should be changed from January 1, 1998, to January 1, 2000. If firms have flexibility to use existing label stocks that do not have folic acid ingredient labeling until January 1, 1998, most of the cost burdens on these firms should be eliminated. The only continuing concern would be if label suppliers could not meet the demand for new labels by January 1, 1998. However, neither NPA nor the comments on the 1993 fortification proposal indicated that large numbers of firms would be faced with such a situation. To the contrary, the agency knows of no reason why most firms cannot acquire new label stocks by that date.

On May 23, 1996, the March of Dimes wrote to FDA that the desire to begin to fortify early was widespread in the industry, but that many firms were not doing so because fortifying their foods would mean that they could not use up existing label stocks (Ref. 3). The March of Dimes suggested that if the agency provided flexibility in the use of label supplies, it would make it more likely that firms would proceed with folic acid fortification at an earlier date, thereby helping to reduce a woman's risk of having a pregnancy affected with spina bifida or other neural tube defects.

Given this significant benefit from folic acid fortification and the significant difficulties in label modification as folic acid is being phased into enriched grain products, FDA advises that, until the amendments to the standards of identity for enriched grain products are effective on January 1, 1998, it is unlikely to take regulatory action against enriched grain products, or products that contain enriched grain products, because the ingredient list in the labeling of such foods fails to include folic acid, or because the nutrition label fails to accurately declare the level of folate, unless folate claims are made for the product. If folate claims are made FDA will expect the food to comply fully with all applicable labeling requirements.

With respect to NPA's request for clarification of the applicability of the effective date, FDA advises that the January 1, 1998, effective date for fortification of standardized enriched grain products applies to the date such products are initially introduced into interstate commerce. FDA does not agree with the NPA suggestion that the effective date should be tied to the date that products are labeled. The agency has for many years used the date of initial introduction into interstate commerce as the effective date for compliance with regulations. Using the date of initial introduction into interstate commerce is a more efficient enforcement approach because this date is easier to determine (e.g., from shipping documents) than the date the food was labeled (from manufacturers' records). Even though the effective date established by the 1990 amendments was the date on which the label was applied to the food, there is no indication in that law or its legislative history that Congress intended that provision to change FDA's approach to effective dates for other labeling requirements from the one the agency has traditionally used.

III. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Centers for Disease Control and Prevention, ''Recommendations for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and Other Neural Tube Defects,'' in *Morbidity and Mortality Weekly Reports*, 41, 1–7, 1992.

2. Kinnaird, Jula J., letter to F. Edward Scarbrough, April 18, 1996.

3. Howse, Jennifer L., letter to Secretary Donna Shalala, May 23, 1996.

Dated: August 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–22606 Filed 9–04–96; 8:45 am]

BILLING CODE 4160–01–F

---

21 CFR Part 177

[Docket No. 84F–0330]

Indirect Food Additives: Polymers

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 copolymer of ethyl acrylate, methyl methacrylate, and methacrylamide in combination with melamine-formaldehyde resin as a coating for polyethylene phthalate films intended for use in contact with food. This action is in response to a petition filed by ICI Americas, Inc.

DATES: Effective September 5, 1996; written objections and requests for a hearing by October 7, 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: Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of October 26, 1984 (49 FR 43111), FDA announced that a food additive petition (FAP 4B3786) had been filed by ICI Americas, Inc., Wilmington, DE 19897. The petition proposed that the food additive regulations be amended to provide for the safe use of a copolymer of ethyl acrylate, methyl methacrylate, and methacrylamide in combination with melamine-formaldehyde resin for use in contact with food in coatings for polyethylene phthalate films as defined by § 177.1630(a) (21 CFR 177.1630(a)).

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 ethyl acrylate, 1,4-dioxane, and ethylene oxide, all of which are carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as ethyl acrylate, 1,4-dioxane, and ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

II. Determination of Safety

Under the so-called ''general safety clause'' 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 clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive, *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984).

III. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, a copolymer of ethyl acrylate, methyl methacrylate, and methacrylamide in combination with melamine-formaldehyde resin, will result in exposure to the additive of no greater than 50 parts per billion (ppb) in the daily diet (Ref. 1).

FDA does not ordinarily consider chronic toxicological testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and has determined that these data support the safety of the additive under the intended conditions of use.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime risk presented by the carcinogenic chemicals that may be present as impurities in the additive. This risk evaluation of the carcinogenic impurities has two aspects: (1) Assessment of the worst-case exposure to the impurities from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

A. Ethyl Acrylate

FDA has estimated the hypothetical worst-case exposure to ethyl acrylate from the petitioned use of the additive in coatings for polyethylene phthalate films to be 8 parts per trillion (ppt) of the daily diet or 24 nanograms per person per day (ng/person/day) (Refs. 1 and 3). The agency used data from the National Toxicology Program report (No. 259:1986), a bioassay on ethyl acrylate, to estimate the upper-bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of the additive (Ref. 4). The results of the bioassay demonstrated that ethyl acrylate was carcinogenic for rats and mice under the conditions of the study. The test material induced squamous cell neoplasms in both sexes of F344/N rats and B6C3F1 mice when administered by gavage in corn oil.

Based on the estimated worst-case exposure to ethyl acrylate of 24 ng/person/day, FDA estimates that the upper-bound limit of individual lifetime risk from exposure to ethyl acrylate from the use of the subject additive is 1.9×10^{-9} (or 2 in 1 billion) (Ref. 5). Because of the numerous conservative assumptions used in calculating the exposure, the actual lifetime-averaged individual exposure to ethyl acrylate is expected to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to ethyl acrylate would result from the proposed use of the additive.

B. Ethylene Oxide

FDA has estimated the hypothetical worst-case exposure to ethylene oxide from the petitioned use of the additive in coatings for polyethylene phthalate films to be 0.04 ppt of the daily diet or 0.12 ng/person/day (Refs. 1 and 3). The agency used data from a carcinogenesis bioassay on ethylene oxide, conducted for the Institute of Hygiene, University of Mainz, Germany, to estimate the upper-bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of the additive (Ref. 6). The results of the bioassay on ethylene oxide demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas of the forestomach and carcinoma in situ of the glandular stomach.

Based on the estimated worst-case exposure to ethylene oxide of 0.12 ng/person/day, FDA estimates that the upper-bound limit of individual lifetime risk from exposure to ethylene oxide from the use of the subject additive is 2.2×10^{-10} (or 2 in 10 billion) (Ref. 5). Because of the numerous conservative assumptions used in calculating the exposure, the actual lifetime-averaged individual exposure to ethylene oxide is expected to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to ethylene oxide would result from the proposed use of the additive.

C. 1,4-Dioxane

FDA has estimated the hypothetical worst-case exposure to 1,4-dioxane from the petitioned use of the additive in coatings for polyethylene phthalate films to be 0.04 ppt of the daily diet or 0.12 ng/person/day (Refs. 1 and 3). The agency used data from a carcinogenesis bioassay on 1,4-dioxane, conducted by the National Cancer Institute, to estimate the upper-bound lifetime human risk from exposure to this chemical stemming from the proposed use of the additive (Ref. 7). The results of the bioassay on 1,4-dioxane demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats.

Based on the estimated worst-case exposure to 1,4-dioxane of 0.12 ng/person/day, FDA estimates that the upper-bound limit of individual lifetime risk from exposure to 1,4-dioxane from the use of the subject additive is 4.2×10^{-12} (or 4 in 1 trillion) (Ref. 5). Because of the numerous conservative assumptions used in calculating the exposure, the actual lifetime-averaged individual exposure to 1,4-dioxane is expected to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to ethylene oxide would result from the proposed use of the additive.

D. Formaldehyde

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. 8) and a negative study by Til et al. (1989), conducted in The Netherlands (Ref. 9). 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. 10). 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.

E. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of ethyl acrylate, ethylene oxide, and 1,4-dioxane present as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which ethyl acrylate, ethylene oxide, and 1,4-dioxane may be expected to remain as impurities following production of the additive, the agency would not expect the impurities to become components of food at other than extremely small levels; and (2) the upper-bound limits of lifetime risk from exposure to the impurities, even under worst-case assumptions, are very low, in the range of less than 4 in 1 trillion to 2 in 1 billion.

IV. Conclusion

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive in coating polyethylene phthalate films is safe, that it will achieve its intended technical effect, and that the regulations in § 177.1630 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.

V. Environmental Impact

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.

VI. 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. Memorandum dated September 20, 1984, from the Food Additive Chemistry Evaluation Branch (HFF–458), to the Petitions Control Branch (HFF–334), entitled ''FAP 4B3786–ICI Americas, Inc. Copolymer coating for polyethylene phthalate films complying with § 177.1630(c). Submission dated 7/30/84 (Rohm & Haas).''

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology'' in ''Chemical Safety Regulation and Compliance,'' edited by F. Homburger, and J. K. Marquis, S. Karger, New York, pp. 24–33, 1985.

3. Memorandum dated October 30, 1992, from the Food and Color Additives Review Section (HFF–415), to the Indirect Additives Branch (HFF–335), concerning FAP 4B3786—ICI Americas, Inc.—exposures acrylamide and methacrylamide, ethyl acrylate, and formaldehyde.

4. ''Carcinogenesis Studies of Ethyl Acrylate (CAS Reg. No. 140–88–5) in F–344/N Rats and B6C3F1 Mice'' (gavage studies), National Toxicology Program, Technical Report Series, No. 259, December 1986.

5. Memorandum, ''Report of the Quantitative Risk Assessment Committee,'' July 1, 1993.

6. Dunkelberg, H., ''Carcinogenicity of Ethylene Oxide and 1,2–Propylene Oxide Upon Intragastric Administration to Rats,'' *British Journal of Cancer*, 46:924–933, 1982.

7. ''Bioassay of 1,4-Dioxane for Possible Carcinogenicity,'' National Cancer Institute, NCI–CG–TR–80, 1978.

8. 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.

9. 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.

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

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before October 7, 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.

List of Subjects in 21 CFR Part 177

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 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 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 177.1630 is amended in paragraph (e)(4) by alphabetically adding a new substance to paragraph (iii) in the ''List of Substances and Limitations'' to read as follows:

§ 177.1630 Polyethylene phthalate polymers.

* * * * *

(e) * * *

(4) * * *

List of Substances and Limitations

* * * * *

(iii) * * *

Acrylic copolymers (CAS Reg. No. 30394–86–6): Prepared by reaction of ethyl acrylate (CAS Reg. No. 140–88–5), methyl methacrylate (CAS Reg. No. 80–62–6), and methyacrylamide (CAS Reg. No. 79–39–0) blended with melamine-formaldehyde resin (CAS Reg. No. 68002–20–0). For use in coatings for polyethylene phthalate films complying with paragraph (a) of this section.

* * * * *

Dated: August 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–22695 Filed 9–4–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Sulfadimethoxine/Ormetoprim Tablets

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 approved NADA provides for oral use of sulfadimethoxine/ormetoprim tablets in dogs for the treatment of certain bacterial skin and soft tissue infections (wounds and abscesses). The supplement adds the treatment of certain bacterial urinary tract infections. This product is limited to veterinary prescription use.

EFFECTIVE DATE: September 5, 1996

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 100–929, which provides for oral use of Primor® (sulfadimethoxine/ormetoprim) tablets in dogs for the treatment of urinary tract infections caused by *Escherichia coli, Staphylococcus* spp., and *Proteus mirabilis* susceptible to the combination of sulfadimethoxine/ormetoprim in addition to its approved use for skin and soft tissue infections (wounds and abscesses) caused by strains of *S. aureus* and *E. coli* susceptible to sulfadimethoxine/ormetoprim. This product is limited to use by or on the order of a licensed veterinarian. The supplement is approved as of August 5, 1996, and the regulations are amended in 21 CFR 520.2220d to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning August 5, 1996, because the supplement contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant. Marketing exclusivity applies only to use in treating urinary tract infections.

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.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.2220d [Amended]

2. Section 520.2220d *Sulfadimethoxine-ormetoprim tablets* is amended in paragraph (c)(2) by adding the phrase ''and urinary tract infections caused by *Escherichia coli, Staphlococcus* spp., and *Proteus mirabilus*'' after ''*Escherichia coli*'' .

Dated: August 23, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–22694 Filed 9–4–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8029]

Furnishing Statements Required With Respect to Certain Substitute Payments; Correction

AGENCY: Internal Revenue Services (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (TD 8029), which were published in the Federal Register on Wednesday, June 5, 1985 (50 FR 23676) relating to statements required to be furnished by brokers and information returns of brokers.

EFFECTIVE DATE: June 5, 1985.

FOR FURTHER INFORMATION CONTACT: Donna Welch, (202) 622–4910, (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of this correction are under sections 6042, 6045 and 6049 of the Internal Revenue Code.

Need for Correction

The final regulations (TD 8029) omitted instructions to remove § 1.6045–2T and the entry for the OMB control number. It is the intent of this document to make these removals as of the publication of the final regulations.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Correcting Amendment to Regulations

Accordingly, 26 CFR parts 1 and 602 are corrected by making the following correcting amendments:

PART 1—INCOME TAXES

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