was published with an error. This certain clinical studies. The document of, any clinical investigator conducting compensation to, and financial interests submit certain information covering the marketing application (applicant), to requiring the sponsor of any drug, Register
``519(k)'' is corrected to read ``510(k)''.

SUPPLEMENTARY INFORMATION:

Food and Drug Administration
21 CFR Part 54

[Docket No. 93N±0445]

Financial Disclosure by Clinical Investigators; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the Federal Register of February 2, 1998 (63 FR 5233). The document issued regulations requiring the sponsor of any drug, including a biological product, or device marketing application (applicant), to submit certain information covering the compensation to, and financial interests of, any clinical investigator conducting certain clinical studies. The document was published with an error. This document corrects that error.


FOR FURTHER INFORMATION CONTACT: Mary C. Gross, Office of External Affairs, Food and Drug Administration (HF±60), 5600 Fisher's Lane, Rockville, MD 20857, 301±827±3440, FAX 301±594±0113.

SUPPLEMENTARY INFORMATION: In FR Doc. 98±2407 appearing on page 5233 in the Federal Register of February 2, 1998, the following correction is made:

§ 54.4 [Corrected]

On page 5251, in the first column, in § 54.4 Certification and disclosure requirements, paragraph (a), line 3, “519(k)” is corrected to read “510(k)”.  

[FR Doc. 98±17145 Filed 6±26±98; 8:45 am]
BILLING CODE 4160±01±F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F±0440]

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 provide for the safe use of N,N-bis(2,2,6,6-tetramethyl-4-piperidinyl)-, polymers with morpholine-2,4,6-trichloro-1,3,5-triazine reaction products, methylated, as a stabilizer for olefin polymers intended for use in contact with food. This action is in response to a petition filed by Cytec Industries, Inc.

DATES: The regulation is effective June 29, 1998; written objections and requests for a hearing by July 29, 1998.

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


SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of November 6, 1997 (62 FR 60095), FDA announced that a food additive petition (FAP 884562) had been filed by Cytec Industries, Inc., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) to provide for the safe use of 1,6-hexanediamine, N,N-bis(2,2,6,6-tetramethyl-4-piperidinyl)-, polymers with morpholine-2,4,6-trichloro-1,3,5-triazine reaction products, methylated, as a stabilizer for olefin polymers complying with 21 CFR 177.1520 intended for use in contact with food.

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 § 178.2010 should be amended as set forth below. FDA's review of this 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 carcogen in 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 turbinate). 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).

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 previously considered the environmental effects of this rule as announced in the notice of filing for
I. Introduction

The Federal Register Notice contains a final rule amendment to 21 CFR part 178 to add a new subsection on the use of 1,6-hexanediamine as a stabilizer in certain food-contact articles. The amendment was made based on the results of two studies: a two-year drinking water study of formaldehyde in rats, and a study of formaldehyde: an experimental multipotential carcinogen. The amendment is effective as of June 19, 1998.

II. Legal Basis

The legal basis for this final rule is 21 U.S.C. 321, 342, 348, and 379e. The amendment is made under the authority delegated to the Commissioner of Food and Drugs and under the Paperwork Reduction Act of 1995.

III. References

The following references have been included in the amendment:

IV. Summary

The amendment to 21 CFR part 178 clarifies the use of 1,6-hexanediamine as a stabilizer in certain food-contact articles. The amendment is effective as of June 19, 1998.