(b) If we are not charging you for the first two hours of search time, under paragraph (c) of § 402.155, and those two hours are spent on a computer search, then the two free hours are the first two hours of the time needed to access the information in the computer.

(c) If we are not charging you for the first 100 pages of duplication, under paragraph (b) or (c) of § 402.155, then those 100 pages are the first 100 pages of photocopies of standard size pages, or the first 100 pages of computer printout.

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[FR Doc. 98–17104 Filed 6–26–98; 8:45 am]
BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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.

EFFECTIVE DATE: February 2, 1999.

FOR FURTHER INFORMATION CONTACT: Mary C. Gross, Office of External Affairs, Food and Drug Administration (HF–60), 5600 Fishers 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)''.

Dated: June 19, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[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 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 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.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 8B4562) 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 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 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.

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

FAP 8B4562 (62 FR 60095, November 6, 1997). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

Any person who will be adversely affected by this regulation may at any time on or before July 29, 1998, 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.

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.

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. Biaggi, ''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: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * * *	* * *
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 (CAS Reg. No. 193098–40–7).	For use only as a stabilizer at levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter. The finished polymers are to contact food only under conditions of use C, D, E, F, and G, as described in Table 2 of § 176.170(c) of this chapter. Provided that the finished food-contact articles have a volume of at least 18.9 liters (5 gallons).
* * * *	* * *

Dated: June 19, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–17144 Filed 6–26–98; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Chapter V

[Docket No. FR–4254–N–03]

HUD Disaster Recovery Initiative

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice of disaster recovery funds availability and waivers; clarification.

SUMMARY: The 1997 Emergency Supplemental Appropriations Act for Recovery from Natural Disasters required publication of a Notice governing use of such funds in conjunction with any program administered by the Federal Emergency Management Agency (FEMA) for buyouts of structures in disaster areas. HUD published a Notice on September 8, 1997 (62 FR 47344) that described the policies and procedures applicable to the HUD Disaster Recovery Initiative. This Notice clarifies the timing of the reports HUD expects to receive on the use of HUD Disaster Recovery Initiative grant funds. This Notice also clarifies the citizen participation certifications and notifies grantees of a statutory restriction on waivers related to funds used as the non-Federal cost-share for U.S. Army Corps of Engineers projects.

EFFECTIVE DATE: June 29, 1998.

FOR FURTHER INFORMATION CONTACT: Jan C. Opper, Senior Program Officer, Office of Block Grant Assistance, Department of Housing and Urban Development, Room 7286, 451 Seventh Street, SW, Washington, DC 20410; telephone number (202) 708–3587. Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339. FAX inquiries may be sent to Mr. Opper at (202) 401–2044. (Except for the