Devon Avenue, Des Plaines, IL 60018, telephone: (847) 294–7477.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 98–15039, Airspace Docket No. 98–AGL–20, published on June 5, 1998 (63 FR 30594) rule modified Class E Airspace at Marion, OH. One error was discovered in the legal description for the Class E airspace for Marion, OH. This action corrects that error. Correction to Final Rule.

Accordingly, pursuant to the authority delegated to me, the legal description for the Class E airspace Marion, OH, as published in the **Federal Register** June 5, 1998 (63 FR 30594), (FR Doc. 98–15039), is corrected as follows:

PART 71—[CORRECTED]

§ 71.1 [Corrected]

AGL OH E5 Marion, OH [Corrected]

On page 30594, Column 3, first line from the top of the column, in the Class E airspace designation for Marion, OH, incorporated by reference in § 71.1, correct the word ''Buckyrus'' to read ''Bucyrus''.

Issued in Des Plaines, IL on June 10, 1998.

David B. Johnson,

Acting Manager, Air Traffic Division, Great Lakes Region.

[FR Doc. 98–16637 Filed 6–16–98; 8:45 am]

BILLING CODE 4910–13–M

FEDERAL TRADE COMMISSION

16 CFR Part 5

Exemption of Insubstantial Financial Conflicts.

AGENCY: Federal Trade Commission (FTC).

ACTION: Final rule.

SUMMARY: The Commission is amending a Commission Rule to make it consistent with the Office of Government Ethics' regulation establishing regulatory waivers of certain financial conflicts of interest.

EFFECTIVE DATE: This amendment is effective on June 29, 1998.

FOR FURTHER INFORMATION CONTACT: Ira S. Kaye, Attorney, Federal Trade Commission, Room 594, 6th Street and Pennsylvania Ave., NW., Washington DC 20580. 202–326–2426.

SUPPLEMENTARY INFORMATION: When the Standards of Ethical Conduct for Employees of the Executive Branch (''Standards''), 5 CFR Part 2635, became effective on February 3, 1993, they superseded most of the Commission's own standards of conduct, 16 CFR Part 5. The Commission rescinded its superseded standards on February 8, 1993. *See* 58 FR 15763 (March 24, 1993). The Commission retained Rule 5.8 because it had not been superseded by the new Standards, but renumbered it as Rule 5.2.

Rule 5.2(a)–(c) provides the requirements and procedures for seeking a waiver of a financial conflict of interest. In addition, Rule 5.2(d) notes that a financial interest in ''[s]tocks and bonds of a diversified mutual fund or investment company'' is waived automatically, pursuant to 18 U.S.C. 208(a), provided that the employee does not own more than one percent of the value of the fund's reported assets.

The U.S. Office of Government Ethics issued a final rule, 5 CFR Part 2640, effective on January 17, 1997, describing a number of additional circumstances under which a financial conflict of interest is waived automatically. For example, an employee may participate in a particular matter, despite holding a financial interest that would be affected by the matter, if the interest arises from the ownership of publicly traded securities and is valued at no more than $5000. 5 CFR 2640.202(a). Thus, the reference to an automatic waiver in Commission Rule 5.2(d) should be amended to reflect the existence of these additional regulatory waivers.

This rule amendment relates solely to agency practice, and, thus, is not subject to the notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. 553(a)(2), or to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601(2).

The amended rule does not involve the ''collection of information'' as that term is defined by the Paperwork Reduction Act (''PRA''), 44 U.S.C. 3501–3520.

List of Subjects in 16 CFR Part 5

Standards of conduct.

For the reasons set forth in the preamble, the Federal Trade Commission amends Title 16, Chapter I, subchapter A, of the Code of Federal Regulations as follows:

PART 5—STANDARDS OF CONDUCT

1. The authorities citation for Part 5 continues to read as follows:

Authority: 5 U.S.C. 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); 15 U.S.C. 46(g); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp. p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306, 5 CFR part 2635, unless otherwise noted.

2. Section 5.2 is amended by revising paragraph (d) to read as follows:

§ 5.2 Exemption of insubstantial financial conflicts.

* * * * *

(d) Pursuant to 5 CFR Part 2640, certain financial interests are exempted from the provisions of 18 U.S.C. 208(a) as being too remote to too inconsequential to affect the integrity of an employee's services.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 98–17232 Filed 6–26–98; 8:45 am]

BILLING CODE 6750–01–M

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 402

RIN 0960–AE68

Electronic Freedom of Information Act Amendments of 1996

AGENCY: Social Security Administration.

ACTION: Final rules.

SUMMARY: These rules reflect the changes made by the Electronic Freedom of Information Act Amendments (EFOIA) of 1996 that give the public access to government information and records maintained in an electronic format, provide for expedited processing of certain requests, establish ''electronic reading rooms,'' eliminate an agency backlog of work as a justification for delay in processing requests, require redacted material to be estimated or indicated in an agency's response, and require an agency reference guide on FOIA to be made available.

EFFECTIVE DATE: These rules are effective July 29, 1998.

FOR FURTHER INFORMATION CONTACT: Ron Martorana, Social Insurance Specialist, 3–A–6 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1745 for information about these rules. For information on eligibility on claiming benefits, call our national toll-free number, 1–800–772–1213.

SUPPLEMENTARY INFORMATION: These rules revise our existing regulations to reflect the provisions of Pub. L. 104–231, the Electronic Freedom of Information Act Amendments of 1996. Pub. L. No. 104–231 amended 5 U.S.C. 552, popularly known as the Freedom of Information Act (FOIA), to provide public access to information in an electronic format, provide for expedited processing of certain requests, establish

''electronic reading rooms,'' eliminate an agency backlog of work as a justification for delay in processing requests, require redacted material to be estimated or indicated in an agency's response, and require an agency reference guide on FOIA to be made available. The rules also make technical changes to related rules.

According to the new law, the term ''record'' encompasses information, subject to the requirements of the FOIA, when maintained in any format, including an electronic format. The category of ''reading room'' records, at 5 U.S.C. 552(a)(2), is expanded to include records that the agency discloses in response to a FOIA request that have become, or are likely to become, the subject of future requests. An index of those records that are subject to multiple requests must be prepared and made available by computer telecommunications by December 31, 1999. Furthermore, agencies must create an ''electronic reading room'' to contain records created after November 1, 1996 that are required to be made available under 5 U.S.C. 552(a)(2). Additionally, agencies must make reasonable efforts to search for records, even when information is maintained in an electronic database, unless such efforts would significantly interfere with the operation of the agency's automated information system. If a requester requests a record in a particular format, agencies must attempt to provide the record in that format if the record is readily reproducible in such format.

The general period for responding to requests has been changed from 10 days to 20 days. Moreover, multi-track processing may be offered as a way to provide more timely responses. Agencies and requesters may discuss alternative time frames to process requests, or modifications to the requests, when the general 20-day time for responding cannot be met. Expedited processing of requests must be done when there is a compelling need for the records. ''Compelling need'' means that the failure to obtain the records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual, or when a request is made by a person primarily engaged in disseminating information (e.g., the news media), and there is an urgency to inform the public concerning actual or alleged Federal Government activity.

The amount of information deleted on a record must be indicated, unless doing so would harm an interest protected by an exemption; and, if technically feasible, the indication shall be at the place in the record where the deletion is made. If whole pages or documents are withheld, an estimate of the volume of material withheld must be provided to the requester, unless doing so would harm an interest protected by an exemption. Furthermore, a guide for requesting records, to include an index and description of major record systems, must be made available to the public.

The definition of ''record'' in § 402.30 is revised to reflect the provisions of section 3 of Pub. L. No. 104–231 to include information stored in an electronic format, and the meaning of ''record'' in the Records Disposal Act, 44 U.S.C. 3301, as well as the Supreme Court's decision in *U.S. Dept. of Justice* v. *Tax Analysts*, 492 U.S. 136 (1989).

Section 402.35 is revised to reflect the provisions of section 4 of Pub. L. No. 104–231 concerning availability of records, extent of deletions, and a general index of records.

Section 402.40 is revised to indicate that SSA Publications on CD–ROM are available for purchase.

Section 402.45 is revised to add a new category to reading room records. These are records which ''the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records.'' Also, we have provided an electronic index for this category of records as reflected in section 4 of the EFOIA amendments.

Section 402.100(b) is revised to reflect the decision in *Dept. of Justice* v. *Reporters Committee for Freedom of the Press*, 489 U.S. 749 (1989) concerning whether personal information may be released. In that case, the Court stated that the only public interest to be considered is whether disclosure would shed light on how an agency performs its statutory duties, and that the identity of the requester or purpose for which the information is requested is not relevant.

Section 402.110, entitled ''Exemption seven for withholding records: Law enforcement'', in 20 CFR 400–499 as revised as of April 1, 1997 is incorrectly designated. It should be designated as § 402.105.

Section 402.115, which explains the deletion of personally identifying details in requested records, and § 402.120, which explains the creation of records, has been moved for ease of reference to § 402.145, which explains what we are required to do when responding to a request for information.

Section 402.130 is revised by adding language about the electronic availability of a guide/handbook on how to request information from the Social Security Administration (SSA). We also describe how the public can request FOIA records.

Section 402.140 is revised to include multi-track processing, requests for expedited processing and the changes in time limits as provided in sections 7 and 8 of the EFOIA amendments. The EFOIA amendments extended the general period of 10 days for determining whether to comply with a request to 20 days.

The EFOIA amendments encourage agencies which experience difficulties in meeting FOIA's time limits to experiment with multi-track processing. Before the enactment of the EFOIA amendments, due to increased volumes of FOIA requests and staff losses, we experimented with various processes to reduce backlogs, among them multi-tracking. The results are encouraging and we plan to institute multi-tracking procedures. We have established four tracks depending on the ease of providing an answer:

(1) Track 1—Requests that can be answered with readily available records or information. These are the fastest to process.

(2) Track 2—Requests where we need records or information from other offices throughout the Agency, but we do not expect that the decision on disclosure will be as time consuming as for requests in Track 3.

(3) Track 3—Requests which require a substantive decision or input from another office or agency and a considerable amount of time will be needed for that, or the request is complicated or involves a large number of records. Usually, these cases will take the longest to process.

(4) Track 4—Requests that will be expedited.

The EFOIA requires agencies to promulgate regulations providing expedited access for requesters who show a ''compelling need'' for a speedy response. The EFOIA describes compelling need as when there is ''an imminent threat to the life or physical safety of an individual,'' or when it is a request from a member of the media, and there is an ''urgency to inform the public concerning actual or alleged Federal Government activity.''

Section 402.145 is revised to include new provisions on searching for, retrieving, and furnishing records in electronic formats, and describes how deletions on records will be indicated.

Section 402.150 is revised to cross-refer to § 402.45 to describe the indexing of records for the new category of reading room records. This describes our procedures for releasing records for which we receive multiple requests or expect to receive multiple requests.

Section 402.160 is revised to correct the reference to § 402.145(b) and (c) and to clarify these paragraphs. These

references should read § 402.155(b) and (c).

Comments on Notice of Proposed Rulemaking

These regulations were published in the **Federal Register** (62 FR 43489) as a notice of proposed rulemaking on August 14, 1997. Interested parties were given 30 days to submit comments. No public comments were received. We are, therefore, publishing these final rules with no substantive changes from the proposed rules.

Regulatory Procedures

Executive Order No. 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these rules do not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, they were not subject to mandatory OMB review.

Regulatory Flexibility Act

We certify that these rules do not have a significant economic impact on a substantial number of small entities since these rules affect only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These regulations impose no additional reporting and recordkeeping requirements subject to OMB clearance.

(Catalog of Federal Domestic Assistance Program Nos. 96.001 Social Security-Disability Insurance; 96.002 Social Security-Retirement Insurance; 96.004 Social Security-Survivors Insurance; 96.006 Supplemental Security Income)

List of Subjects in 20 CFR 402

Administrative practice and procedure, Freedom of information, Reporting and recordkeeping.

Dated: June 18, 1998.

Kenneth S. Apfel,

Commissioner of Social Security.

For the reasons set out in the preamble, we are amending part 402 of 20 CFR chapter III as follows:

PART 402—AVAILABILITY OF INFORMATION AND RECORDS TO THE PUBLIC

1. The authority citation for 20 CFR part 402 continues to read as follows:

Authority: Secs. 205, 702(a)(5), and 1106 of the Social Security Act; (42 U.S.C. 405, 902(a)(5), and 1306); Section 413(b) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 923b), 5 U.S.C. 552 and 552a; 8 U.S.C. 1360; 18 U.S.C. 1905; 26 U.S.C. 6103; 31 U.S.C. 9701; E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235.

2. Section 402.30 is amended by revising the definition of ''records'' to read as follows:

§ 402.30 Definitions.

* * * * *

Records means any information maintained by an agency, regardless of forms or characteristics, that is made or received in connection with official business. This includes handwritten, typed, or printed documents (such as memoranda, books, brochures, studies, writings, drafts, letters, transcripts, and minutes) and material in other forms, such as punchcards; magnetic tapes; cards; computer discs or other electronic formats; paper tapes; audio or video recordings; maps; photographs; slides; microfilm; and motion pictures. It does not include objects or articles such as exhibits, models, equipment, and duplication machines, audiovisual processing materials, or computer software. It does not include personal records of an employee, or books, magazines, pamphlets, or other reference material in formally organized and officially designated SSA libraries, where such materials are available under the rules of the particular library.

* * * * *

3. Section 402.35 is amended by adding new paragraph (d) to read as follows:

§ 402.35 Publication.

* * * * *

(d) *Availability by Telecommunications.* To the extent practicable, we will make available by means of computer telecommunications the indices and other records that are available for inspection.

4. Section 402.40 is amended by adding new paragraph (h) to read as follows:

§ 402.40 Publications for sale.

* * * * *

(h) SSA Publications on CD–ROM.

5. Section 402.45 is amended by adding new paragraph (d) to read as follows:

§ 402.45 Availability of records.

* * * * *

(d) *Electronic Reading Room.* We will prepare an index of records which have become or are likely to become the subject of subsequent requests. The index, and, to the extent practicable, the records will be made available on the Internet or by other computer telecommunications means.

6. Section 402.100 is amended by revising the heading and paragraph (b) to read as follows:

§ 402.100 Exemption six: Clearly unwarranted invasion of personal privacy.

* * * * *

(b) *Balancing test.* In deciding whether to release records to you that contain personal or private information about someone else, we weigh the foreseeable harm of invading a person's privacy against the public interest in disclosure. In determining whether disclosure would be in the public interest, we will consider whether disclosure of the requested information would shed light on how a Government agency performs its statutory duties. However, in our evaluation of requests for records we attempt to guard against the release of information that might involve a violation of personal privacy because of a requester being able to ''read between the lines'' or piece together items that would constitute information that normally would be exempt from mandatory disclosure under Exemption Six.

* * * * *

7. The first § 402.110 entitled ''Exemption seven for withholding records: Law enforcement'' is amended by correctly designating the section number to read § 402.105.

§ 402.115 [Removed]

8. Section 402.115 is removed.

§ 402.120 [Removed]

9. Section 402.120 is removed.

10. Section 402.130 is revised to read as follows:

§ 402.130 How to request a record.

You may request a record in person or by mail or by electronic telecommunications. To the extent practicable, and in the future, we will attempt to provide access for requests by telephone, fax, Internet, and e-mail. Any request should reasonably describe the record you want. If you have detailed information which would assist us in identifying that record, please submit it with your request. We may charge fees for some requests (§§ 402.145–402.175 explain our fees). You should identify the request as a Freedom of Information Act request and mark the outside of any envelope used to submit your request as a ''Freedom of Information Request.'' The staff at any Social Security office can help you prepare this request.

11. Section 402.140 is revised to read as follows:

§ 402.140 How a request for a record is processed.

(a) In general, we will make a determination as to whether a requested record will be provided within 20 days (excepting Saturdays, Sundays, and legal public holidays) after receipt of a request by the appropriate official (see § 402.135). This 20-day period may be extended in unusual circumstances by written notice to you, explaining why we need additional time, and the extension may be for up to 10 additional working days when one or more of the following situations exist:

(1) The office processing the request needs to locate and then obtain the record from another facility;

(2) We need to locate, obtain, and appropriately examine a large number of records which are requested in a single request; or

(3) The office processing the request needs to consult with another agency which has a substantial interest in the subject matter of the request. This consultation shall be conducted with all practicable speed.

(b) If we cannot process your request within 10 additional days, we will notify you and provide you an opportunity to limit the scope of the request so that it may be processed within the additional 10 days, or we will provide you with an opportunity to arrange with us an alternative time frame for processing the request, or for processing a modified request.

(c) *Multi-tracking procedures.* We will establish four tracks for handling requests and the track to which a request is assigned will depend on the nature of the request and the estimated processing time:

(1) Track 1—Requests that can be answered with readily available records or information. These are the fastest to process.

(2) Track 2—Requests where we need records or information from other offices throughout the Agency but we do not expect that the decision on disclosure will be as time consuming as for requests in Track 3.

(3) Track 3—Requests which require a decision or input from another office or agency and a considerable amount of time will be needed for that, or the request is complicated or involves a large number of records. Usually, these cases will take the longest to process.

(4) Track 4—Requests that will be expedited.

(d) We will provide for expedited access for requesters who show a ''compelling need'' for a speedy response. The EFOIA describes compelling need as when the failure to obtain the records on an expedited basis could reasonably be expected to pose ''an imminent threat to the life or physical safety of an individual,'' or when the request is from a person primarily engaged in disseminating information (such as a member of the news media), and there is an ''urgency to inform the public concerning actual or alleged Federal Government activity.'' We also will expedite processing of a request if the requester explains in detail to our satisfaction that a prompt response is needed because the requester may be denied a legal right, benefit, or remedy without the requested information, and that it cannot be obtained elsewhere in a reasonable amount of time. We will respond within 10 days to a request for expedited processing and, if we decide to grant expedited processing, we will then notify you of our decision whether or not to disclose the records requested as soon as practicable.

12. Section 402.145 is revised to read as follows:

§ 402.145 Responding to your request.

(a) *Retrieving records.* We are required to furnish copies of records only when they are in our possession or we can retrieve them from storage. We will make reasonable efforts to search for records manually or by automated means, including any information stored in an electronic form or format, except when such efforts would significantly interfere with the operation of our automated information system. If we have stored the records you want in the National Archives or another storage center, we will retrieve and review them for possible disclosure. However, the Federal Government destroys many old records, so sometimes it is impossible to fill requests. Various laws, regulations, and manuals give the time periods for keeping records before they may be destroyed. For example, there is information about retention of records in the Records Disposal Act of 1944, 44 U.S.C. 3301 through 3314; the Federal Property Management Regulations, 41 CFR 101–11.4; and the General Records Schedules of the National Archives and Records Administration.

(b) *Furnishing records.* We will furnish copies only of records that we have or can retrieve. We are not required to create new records or to perform research for you. We may decide to conserve Government resources and at the same time supply the records you need by consolidating information from various records rather than copying them all. For instance, we could extract sections from various similar records instead of providing repetitious information. We generally will furnish only one copy of a record. We will make reasonable efforts to provide the records in the form or format you request if the record is readily reproducible in that form or format.

(c) *Deletions.* When we publish or otherwise make available any record, we may delete information that is exempt from disclosure. For example, in an opinion or order, statement of policy, or other record which relates to a private party or parties, the name or names and other identifying details may be deleted. When technically feasible, we will indicate the extent of deletions on the portion of the record that is released or published at the place of the deletion unless including that indication would harm an interest protected by an exemption. If we deny a request, in whole or in part, we will make a reasonable effort to estimate the volume of any requested matter that is not disclosed, unless such an estimate would harm an interest protected by an exemption.

(d) *Creation of records.* We are not required to create new records merely to satisfy a request. However, we will search manually or by automated means to locate information that is responsive to the request. If extensive computer programming is needed to respond to a request, we may decline to commit such resources, or if we agree to do so, we may charge you for the reasonable cost of doing so. We do not mean that we will never help you get information that does not already exist in our records. However, diverting staff and equipment from our other responsibilities may not always be possible.

13. Section 402.150 is amended by revising paragraph (a), removing paragraph (b), and redesignating paragraph (c) as new paragraph (b) to read as follows:

§ 402.150 Release of records.

(a) *Records previously released.* If we have released a record, or a part of a record, to others in the past, we will ordinarily release it to you also. However, we will not release it to you if a statute forbids this disclosure, and we will not necessarily release it to you if an exemption applies in your situation and it did not apply, or applied differently, in the previous situation(s) or if the previous release was unauthorized. See § 402.45(d) regarding records in electronic reading rooms.

* * * * *

14. Section 402.160 is amended by revising paragraphs (b) and (c) to read as follows:

§ 402.160 Fees to be charged—general provisions.

* * * * *

(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.

* * * * *

[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