DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 740 and 748

[Docket No. 010112014–1014–01]

RIN 0694–AC41

Implementation of Presidential Announcement of January 10, 2001: Revisions to License Exception CTP; Corrections

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: On January 19, 2001 the Bureau of Export Administration (BXA) published a final rule revising License Exception CTP. This rule corrects inadvertent citation references in the January 19 rule.

DATES: This rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Sharron Cook in the Office of Exporter Services, Bureau of Export Administration, at (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. This regulation involves collections previously approved by the Office of Management and Budget under control numbers 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 45 minutes per manual submission and 40 minutes per electronic submission. Miscellaneous and recordkeeping activities account for 12 minutes per submission. Information is also collected under OMB control number 0694–0107, ''National Defense Authorization Act,'' Advance Notifications and Post-Shipment Verification Reports, which carries a burden hour estimate of 15 minutes per report. This rule also involves collections of information under OMB control number 0694–0073, ''Export Controls of High Performance Computers'' and OMB control number 0694–0093, ''Import Certificates and End-User Certificates.''

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act requiring notice of proposed rule making, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rule making and an opportunity for public comment be given for this rule. Because a notice of proposed rule making and opportunities for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Office of Exporter Services, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects in 15 CFR Parts 740 and 748

Administrative practice and procedure, Exports, Foreign trade, Reporting and record keeping requirements.

Accordingly, parts 740 and 748 of the Export Administration Regulations (15 CFR Parts 730–799) are amended as follows:

1. The authority citation for 15 CFR Part 740 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; 50 U.S.C. 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

2. The authority citation for part 748 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; 50 U.S.C. 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

PART 740—CORRECTED

3. Part 740 is corrected by revising the phrase ''paragraph (d)(2)'' to read ''paragraphs (d)(5)(i)(A) or (d)(5)(i)(B)'' in paragraph 740.7(d)(4).

PART 748—CORRECTED

4. Section 748.10 is corrected by revising the citation reference ''§ 740.7(d)(2)'' to read ''§ 740.7(d)(5)(i)(A) or § 740.7(d)(5)(i)(B)'' in paragraph (b)(3)(i).

Dated: January 17, 2001.

Eileen M. Albanese,

Director, Office of Exporter Services, Export Administration.

[FR Doc. 01–1863 Filed 1–19–01; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 14, and 16

[Docket No. 98–1042]

Revision of Administrative Practices and Procedures; Meetings and Correspondence; Public Calendars

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations relating to meetings, correspondence, and the agency's public calendar. This action makes FDA's procedures more concise and understandable to the public, minimizes confusion about publicly available information concerning agency meetings, provides for more effective disclosure of such information, and allows the FDA to reallocate resources to areas of more urgent public health need.

DATES: This rule is effective January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Brian Mayhew, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5211, e-mail: bmayhew@oc.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 17, 1998 (63 FR 69575), FDA issued a proposed rule to modify certain regulations pertaining to the public calendar and public meetings because such regulations are no longer effective in serving their intended purposes.

In that proposed rule, FDA tentatively concluded that the proposed action would make its procedures for public calendars and public meetings more concise and understandable to the public, minimize confusion about publicly available information

concerning agency meetings, provide for more effective disclosure of such information, and allow FDA to reallocate resources to areas of more urgent public health need.

Interested parties were given until March 2, 1999, to comment on the proposal. Three letters, each containing one or more comments, were received in response to the proposal. Such letters were from a research laboratory, a blood bank association, and a research institute. The blood bank association supported the proposal, while the two other organizations suggested a number of modifications. The comments received and FDA's responses are addressed below.

II. Comments and Agency Response

A. The Prospective Public Calendar

(Comment 1) The proposed regulation would eliminate the prospective public calendar. Three comments addressed the elimination. One comment suggested that FDA evaluate whether the use of the prospective public calendar affects participation in FDA sponsored events before eliminating the prospective public calendar. Another comment noted that the proposed rule included no data to support the agency's tentative conclusion that maintenance of the prospective public calendar is no longer practical, workable, or beneficial to the public.

While the agency has not formally studied the impact of the public calendar on the amount of participation in a public event, FDA notes that it generally does a great deal of outreach through other mechanisms, including the **Federal Register**, the Internet, direct mailings, and other direct communications. In fact, the prospective public calendar may be one of the least effective mechanisms for notifying the public of upcoming public events, given that maintenance of the calendar has been given a lower priority and fewer resources have been expended to ensure that information on the public calendar is accurate and current. FDA has not performed a study regarding the maintenance of the public calendar either. However, the agency believes that it is much more efficient to allocate its limited resources to more effective methods of communication to its stakeholders.

(Comment 2) One comment requested that FDA not abandon any important communication mechanism such as the prospective public calendar that is designed to fulfill its obligation to notify the participants about future events until it fully examines whether some simple improvements to the existing system will fix problems for FDA and the public.

Due to the extremely positive response that the agency receives at its public meetings, public hearings, and other widely-attended events, the agency believes that other mechanisms, such as the Internet and the **Federal Register**, are effectively communicating the relevant information about FDA events. FDA does not believe that simple improvements to the current prospective public calendar will significantly improve its effectiveness.

(Comment 3) One comment asserted that the reasons provided for removing the prospective public calendar (i.e., need for frequent changes to the calendar, difficulty in projecting entries 4 weeks in advance) do not appear sufficient to warrant elimination of the availability of this information from the general public, especially in light of the resources expended on direct mail, the **Federal Register**, and FDA Internet activities.

The agency notes that it is precisely because of the availability of these other mechanisms that it is deleting the prospective public calendar requirements from its regulations. The agency will continue to use these very effective and efficient mechanisms in the future. Resources devoted to these other mechanisms will more adequately ensure that the public receives information regarding FDA meetings than if those same resources were devoted to maintaining the prospective public calendar.

(Comment 4) One comment stressed the importance of the agency providing adequate advance time for its announcements through other mechanisms.

The agency agrees with this comment, and it will strive to ensure that adequate time will be provided to the public when it disseminates information about public events via the Internet, the **Federal Register**, or other mechanisms.

(Comment 5) One comment suggested that with the abandonment of the prospective public calendar, it is extremely important that FDA maintain the timely publication of all meeting summaries because they are important and useful to the public.

FDA agrees with this comment.

(Comment 6) One comment argued that it was unrealistic to expect that the public at large is able to access the same information via the Internet as in the publication it plans to discontinue.

The agency believes that Internet access has become increasingly widespread in recent years. However, even in the event that a person did not have Internet access, other mechanisms, including **Federal Register** notices and direct mail, will provide adequate notification to the public regarding information previously contained in the prospective public calendar.

B. The Retrospective Public Calendar

(Comment 7) Under the proposed regulations, only meetings between certain senior agency officials and persons outside the executive branch of Government would be included on the retrospective public calendar. If a large number of persons is in attendance at a meeting, the name of each person need not be specified in the calendar entry, and if more than one FDA representative is in attendance, only the most senior official would report the meeting. One comment stated that these proposed changes would significantly limit the availability of potentially important information and would significantly restrict the range of input reflecting the various levels within FDA.

As stated in the proposed rule (63 FR 69575), the agency finds that it has become unduly burdensome for assistants, deputies, and representatives of the agency's senior officials to report meetings. FDA anticipates that despite this limitation on the reporting of some meetings, those meetings that are of greatest interest to the public will be reflected on the retrospective public calendar, thereby providing an appropriate level of public access to information.

C. Public Meetings

(Comment 8) Under the proposed regulations, FDA representatives may determine when it is appropriate to create an official transcript, recording, or memorandum of a meeting. One comment stated that, due to these changes in § 10.65(b) through (f) (21 CFR 10.65(b) through (f)), the availability of potentially important information will be denied to the public.

Because of limited resources, the agency finds that the determination of whether memoranda of a given meeting should be prepared should be left to the discretion of the senior agency official attending the meeting, taking into consideration the subject matter of the meeting, the public interest in the issue, and the value of using agency resources to prepare such transcripts, recordings, or memoranda. The agency does not believe that this change will significantly diminish the amount of important information made available to the public. This change will allow resources to be redirected to areas of greater public health need. This change does not preclude a participant from

preparing a summary of the meeting for inclusion into the administrative record, regardless of whether the agency creates an official record.

(Comment 9) Under the proposed regulations, meetings may be public or private at FDA's discretion. One comment requested that FDA exclude any individual representing a company that is the sponsor of an application pending before the agency from the definition of ''person outside the Federal government.'' The reason for this request was that the comment did not want such an individual to have his/her meeting denied in favor of a meeting with a larger audience, raising issues about confidential business information.

The agency will not schedule larger meetings in place of necessary meetings with a sponsor of a product with an application pending before the agency. Instead, this clarification in the regulation is intended to provide the agency with the discretion to combine certain meeting requests of a similar nature. The agency has no intention of denying necessary meetings with sponsors where confidential information may be discussed. The comment misinterpreted the intent of the amendment, and the agency does not, therefore, find it necessary to change the definition of ''person outside the Federal Government''

(Comment 10) One comment suggested that FDA should publish the criteria that it uses in making a determination about whether a meeting should be public or private.

The agency believes that this comment suggests a more elaborate process for this determination than the agency contemplated or than the agency believes necessary. While FDA is increasingly striving to make its processes open, transparent, and predictable, the agency is continuing to minimize an unnecessary burden on itself or its constituents. The agency reserves the discretion to make determinations about whether a given meeting is public or private on an informal and largely ad hoc basis. However, to the extent possible, FDA will make every effort to honor meeting requests and make its meetings as open and accessible to the public as practical.

(Comment 11) One comment suggested that the agency clarify that if other publicly available documents, such as hearing transcripts, congressional letters, and hearing testimony were not issued in a timely fashion from other sources, FDA will then issue a memorandum.

The agency declines to commit to issuing of a meeting memorandum whenever other sources do not make other documents available. However, FDA will make every effort to ensure that information about meetings with Congress covered by this rule is available as quickly as possible.

III. Changes From the Proposed Rule

Proposed revised § 10.65(e)(1) and (e)(2) have been modified and redesignated as § 10.65(f) to provide information about the filing of memoranda or summaries in the administrative file.

Proposed revised § 10.65(k) has been deleted because the statutory requirement upon which it was based has been repealed. (Public Law 105–362, title VI, section 601(a)(2)(A), 112 Stat. 3285 (1998).)

In this final rule, the agency is amending § 10.100(b)(3) (21 CFR 10.100(b)(3)) to more accurately reflect the current personnel structure of the agency. A reorganization of the Office of the Commissioner of Food and Drugs (the Commissioner) has changed the organizational structure of that office. This reorganization reduces the number of senior officials who would be covered by § 10.100 (b)(3). Therefore, only the Commissioner, Senior Associate Commissioners, Deputy Commissioners, Associate Commissioner for Regulatory Affairs, Center Directors, and the Chief Counsel will be required to report meetings on the retrospective calendar.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that would not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement would be required.

V. Analysis of Impact

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public L. 104–121)) and the Unfunded Mandates Reform Act of 1995 (Pub. Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

The Regulatory Flexibility Act requires an analysis of regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any one year. The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. This final rule does not impose any mandates on State, local, or tribal governments, nor is it a significant regulatory action under the Unfunded Mandates Reform Act. Furthermore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further regulatory flexibility analysis is required.

VI. Paperwork Reduction Act of 1995

This regulation would impose no reporting or recordkeeping requirements that would necessitate Office of Management and Budget clearance.

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 10, 14, and 16 are amended to read as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461, 21 U.S.C. 141–149, 321–397, 467f, 679, 821 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 10.30 [Amended]

2. Section 10.30 *Citizen petition* is amended in paragraph (i)(6) by removing ''§ 10.65(h)'' and adding in its place ''§ 10.65(f)''.

§ 10.33 [Amended]

3. Section 10.33 *Administrative reconsideration of action* is amended in paragraph (k)(6) by removing

''§ 10.65(h)'' and adding in its place ''§ 10.65(f)''.

§ 10.35 [Amended]

4. Section 10.35 *Administrative stay of action* is amended in paragraph (h)(6) by removing ''§ 10.65(h)'' and adding in its place ''§ 10.65(f)''.

§ 10.40 [Amended]

5. Section 10.40 *Promulgation of regulations for the efficient enforcement of the law* is amended in paragraph (g)(7) by removing ''§ 10.65(h)'' and adding in its place ''§ 10.65(f)''.

6. Section 10.65 is revised to read as follows:

§ 10.65 Meetings and correspondence.

(a) In addition to public hearings and proceedings established under this part and other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of FDA and an interested person outside FDA on a matter within the jurisdiction of the laws administered by the Commissioner. Action on meetings and correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(b) The Commissioner may conclude that it would be in the public interest to hold an open public meeting to discuss a matter (or class of matters) pending before FDA, in which any interested person may participate.

(1) The Commissioner shall inform the public of the time and place of the meeting and of the matters to be discussed.

(2) The meeting will be informal, i.e., any interested person may attend and participate in the discussion without prior notice to the agency unless the notice of the meeting specifies otherwise.

(c) Every person outside the Federal Government may request a private meeting with a representative of FDA in agency offices to discuss a matter. FDA will make reasonable efforts to accommodate such requests.

(1) The person requesting a meeting may be accompanied by a reasonable number of employees, consultants, or other persons with whom there is a commercial arrangement within the meaning of § 20.81(a) of this chapter. Neither FDA nor any other person may require the attendance of a person who is not an employee of the executive branch of the Federal Government without the agreement of the person requesting the meeting. Any person may attend by mutual consent of the person requesting the meeting and FDA.

(2) FDA will determine which representatives of the agency will attend the meeting. The person requesting the meeting may request, but not require or preclude, the attendance of a specific FDA employee.

(3) A person who wishes to attend a private meeting, but who is not invited to attend either by the person requesting the meeting or by FDA, or who otherwise cannot attend the meeting, may request a separate meeting with FDA to discuss the same matter or an additional matter.

(d) FDA employees have a responsibility to meet with all segments of the public to promote the objectives of the laws administered by the agency. In pursuing this responsibility, the following general policy applies where agency employees are invited by persons outside the Federal Government to attend or participate in meetings outside agency offices as representatives of the agency.

(1) A person outside the executive branch may invite an agency representative to attend or participate in a meeting outside agency offices. The agency representative is not obligated to attend or participate, but may do so where it is in the public interest and will promote the objectives of the act.

(2) The agency representative may request that the meeting be open if that would be in the public interest. The agency representative may decline to participate in a meeting held as a private meeting if that will best serve the public interest.

(3) An agency representative may not knowingly participate in a meeting that is closed on the basis of gender, race, or religion.

(e) An official transcript, recording, or memorandum summarizing the substance of any meeting described in this section will be prepared by a representative of FDA when the agency determines that such documentation will be useful.

(f) FDA promptly will file in the appropriate administrative file memoranda of meetings prepared by FDA representatives and all correspondence, including any written summary of a meeting from a participant, that relate to a matter pending before the agency.

(g) Representatives of FDA may initiate a meeting or correspondence on any matter concerning the laws administered by the Commissioner. Unless otherwise required by law, meetings may be public or private at FDA's discretion.

(h) A meeting of an advisory committee is subject to the requirements of part 14 of this chapter.

7. Section 10.100 is revised to read follows:

§ 10.100 Public calendar.

(a) *Public calendar.* A public calendar will be prepared and made publicly available by FDA each week showing, to the extent feasible, significant events of the previous week, including significant meetings with persons outside the executive branch, that involve the representatives of FDA designated under paragraph (c) of this section.

(1) Public calendar entries will include:

(i) Significant meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision;

(ii) Significant meetings, conferences, seminars, and speeches; and

(iii) Social events sponsored by the regulated industry.

(2) The public calendar will not include reports of meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment at FDA), meetings with members of the press, or meetings with onsite contractors.

(b) *Calendar entries.* The calendar will specify for each entry the date, person(s), and subject matter involved. If a large number of persons are in attendance, the name of each individual need not be specified. When more than one FDA representative is in attendance, the most senior agency official will report the meeting on the public calendar.

(c) *Affected persons.* The following FDA representatives are subject to the requirements of this section:

(1) Commissioner of Food and Drugs.

(2) Senior Associate Commissioners.

(3) Deputy Commissioners.

(4) Associate Commissioner for Regulatory Affairs.

(5) Center Directors.

(6) Chief Counsel for the Food and Drug Administration.

(d) *Public display.* The public calendar will be placed on public display at the following locations:

(1) Dockets Management Branch.

(2) Office of the Associate Commissioner for Public Affairs.

(3) The FDA home page, to the extent feasible.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

8. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394,

467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 14.20 [Amended]

9. Section 14.20 *Notice of hearing before an advisory committee* is amended by removing paragraph (e).

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

10. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

§ 16.60 [Amended]

11. Section 16.60 *Hearing procedure* is amended by removing paragraph (a)(3).

Dated: January 5, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–1566 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 99F–2336]

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 manganese ammonium pyrophosphate (C.I. Pigment Violet 16) as a colorant for all polymers intended for use in contact with food. This action is in response to a petition filed by Holliday Pigments, Ltd.

DATES: This rule is effective January 22, 2001. Submit written objections and requests for a hearing by February 21, 2001.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 21, 1999 (64 FR 39146), FDA announced that a food additive petition (FAP 9B4670) had been filed by Holliday Pigments, Ltd., Morley St., Kingston upon Hull, HU8 8DN ENGLAND. The petition proposed to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of manganese ammonium pyrophosphate (C.I. Pigment Violet 16) as a colorant for all polymers intended for use in contact with food.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 178.3297 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.

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.

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.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by February 21, 2001. 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 are to be submitted 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 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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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 178.3297 is amended in the table in paragraph (e) by alphabetically adding an entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *