ethoxylated tallow alkyl amines, in the manufacture of paper and paperboard. Subject of Food Additive Petition 8B4576 (Sequa Chemicals, Inc.), dated May 21, 1998.

List of Subjects in 21 CFR Part 176

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 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

2. Section 176.180 is amended in the table in paragraph (b)(2) by alphabetically adding an entry under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 176.180 Components of paper and paperboard in contact with dry food.

* * * * *

(b) * * *

(2) * * *

List of substances	Limitations
* * * * * * *	
Octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol and urea (CAS Reg. No. 68412–14–6), and the acetate salts thereof (CAS Reg. No. 68784–21–4), which may be emulsified with ethoxylated tallow alkyl amines (CAS Reg. No. 61791–26–2).	For use prior to sheet forming at levels not to exceed 12 pounds per ton of paper.
* * * * * * *	

Dated: October 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29616 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 98F–0432]

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 chromium oxide green, Cr_2O_3 (C.I. Pigment Green 17) as a colorant for polymers intended for use in contact with food. This action is in response to a petition filed by Ticona.

DATES: The regulation is effective November 5, 1998; written objections and requests for a hearing by December 7, 1998.

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: 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 June 22, 1998 (63 FR 33935), FDA announced that a food additive petition (FAP 8B4603) had been filed by Ticona, 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 § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of chromium oxide green, Cr_2O_3 (C.I. Pigment Green 17) as a colorant for polymers 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, 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 previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8B4603 (63 FR 33935). 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.

This final rule contains no collection 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 on or before December 7, 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.

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 revising the entry for ''Chromium oxide green'' under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
Chromium oxide green, Cr_2O_3 (C.I. Pigment Green 17, C.I. No. 77288).	For use only: 1. In polymers used in contact with food at a level not to exceed 5 percent by weight of the polymer, except as specified below. 2. In olefin polymers complying with § 177.1520 of this chapter. 3. In repeat-use rubber articles complying with § 177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber articles.
* * *	* * * *

Dated: October 15, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–29562 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 85N–0214]

Effective Date of Approval of an Abbreviated New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule; opportunity for public comment.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim rule to amend its regulations establishing the effective date of approval of abbreviated new drug applications (ANDA's). The interim rule eliminates the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180 days of marketing exclusivity.

DATES: The interim rule is effective November 10, 1998. Submit written comments by February 3, 1999.

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

FOR FURTHER INFORMATION CONTACT: Virginia G. Beakes or Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the Hatch-Waxman Amendments) amended the Federal Food, Drug, and Cosmetic Act (the act). The Hatch-Waxman Amendments created section 505(j) of the act (21 U.S.C. 355(j)). Section 505(j) created the current ANDA approval process, which allows lower-priced generic versions of previously approved innovator drugs to be approved and brought on the market.

Innovator drug applicants must include in their new drug application (NDA) information about patents that claim the drug product that is the subject of the NDA. FDA publishes this patent information as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.''

An ANDA applicant must include in the ANDA a patent certification described in section 505(j)(2)(A)(vii) of the act. The certification must make one of the following statements: (1) That no patent information on the drug product that is the subject of the ANDA has been submitted to FDA; (2) that such patent has expired; (3) the date on which such patent expires; or (4) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDA is submitted. This last certification is known as a ''paragraph IV certification.'' A notice of the paragraph IV certification must be provided to each owner of the patent which is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. The submission of an ANDA for a drug product that is claimed in a patent is an infringing act, if that drug product is intended to be marketed before the expiration of the patent, and may be the basis for patent litigation.

Section 505(j)(5)(B)(iv)[1] of the act provides an incentive for generic manufacturers to challenge patents that may be invalid or unenforceable by filing paragraph IV certifications, thereby inviting a patent action against them by the patent owner. Section 505(j)(5)(B)(iv) of the act states that:

If the [ANDA] contains a [paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection continuing [sic] such a certification, the application shall be made

[1] Prior to the enactment of the Food and Drug Administration Modernization Act (the Modernization Act) of 1997, 180-day exclusivity was described at section 505(j)(4)(B)(iv) of the act. The Modernization Act added new provisions to section 505(j) that resulted in a renumbering of the sections.