

SUMMARY: The Employment and Training Administration (ETA) and the Employment Standards Administration (ESA) of the Department of Labor (DOL or Department) are hereby announcing an enforcement policy regarding a provision of the regulations governing the enforcement of labor condition applications filed by employers seeking to employ foreign workers in specialty occupations and as fashion models of distinguished merit and ability under the H-1B nonimmigrant visa classification. Under the Immigration and Nationality Act (INA), an employer seeking to employ such a nonimmigrant is required to file a labor condition application with DOL before the Immigration and Naturalization Service (INS) may approve an H-1B visa petition. The labor condition application process is administered by ETA; complaints and investigations regarding labor condition applications are the responsibility of ESA.

EFFECTIVE DATE: September 26, 1995.

FOR FURTHER INFORMATION CONTACT: On 20 CFR part 655, subpart H, and 29 CFR part 507, subpart H, contact Flora T. Richardson, Chief, Division of Foreign Labor Certifications, U.S. Employment Service, Employment and Training Administration, Department of Labor, Room N-4456, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 219-5263 (this is not a toll-free number).

On 20 CFR part 655, subpart I, and 29 CFR part 507, subpart I, contact Chief, Branch of Farm Labor and Immigration Programs, Wage and Hour Division, Employment Standards Administration, Department of Labor, Room S-3502, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 219-7605 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Secretary of Labor's Final Rule (December 20, 1994, 59 FR 65646) regarding the H-1B nonimmigrant program became effective on January 19, 1995. Section _____.731(b)(1) of the Final Rule requires that, in documenting its compliance with the wage requirements, an employer shall maintain at least the information listed in § _____.731(b)(1)(i) through (vii), not only for the H-1B nonimmigrant(s), but for "all other employees for the specific employment in question at the place of employment." The prior Interim Final Rule (January 13, 1992, 57 FR 1316), at § _____.730(e)(2)(i), required that the employer maintain documentation of the listed items for "all other individuals with experience and qualifications similar to the H-1B nonimmigrant for the specific

employment in question at the place of employment."

Enforcement Position

The Department hereby announces that, with respect to any additional workers for whom the Final Rule may have applied the recordkeeping requirements at § _____.731(b)(1), it will enforce this provision to require the employer to keep only those records which are required by the Fair Labor Standards Act ("FLSA"), 29 CFR Part 516. In virtually all situations, the Department anticipates that the records required by the FLSA include those listed under the H-1B Final Rule.

Signed at Washington, D.C., this 20th day of September, 1995.

John R. Beverly, III,

Deputy Director, United States Employment Service.

John Fraser,

Deputy Administrator, Wage and Hour Division.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 94F-0005]

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 oxidized bis(hydrogenated tallow alkyl)amines as a process stabilizer for polypropylene intended for use in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective September 26, 1995; written objections and requests for a hearing by October 26, 1995.

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

FOR FURTHER INFORMATION CONTACT: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3080.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of February 24, 1994 (59 FR 8995), FDA announced that a food additive petition (FAP 4B4410) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532. The petition proposed that the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of oxidized bis(hydrogenated tallow alkyl)amines (CAS Reg. No. 143925-92-2) as a process stabilizer for polypropylene intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency is not including the Chemical Abstracts Service Registry number (CAS Reg. No. 143925-92-2) in the regulation because it corresponds to the pure hydroxylamine component of the additive and not to the additive itself. The agency concludes that the proposed food additive use is safe, and that the regulations in § 178.2010 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 21 CFR 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.

Any person who will be adversely affected by this regulation may at any time on or before October 26, 1995, 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: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (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
* * *	* * *
Oxidized bis(hydrogenated tallow alkyl)amines.	For use only at levels not to exceed 0.05 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, or 1.3: The finished polymers may be used in contact with food types I, II, IV-B, VII-B, and VIII described in Table 1 of § 176.170(c) of this chapter, under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter, and with food types III, IV-A, V, VI, VII-A, and IX described in Table 1 of § 176.170(c) of this chapter, under conditions of use D through H described in Table 2 of § 176.170(c) of this chapter.

Dated: September 13, 1995.
 Janice F. Oliver,
*Deputy Director for Systems and Support,
 Center for Food Safety and Applied Nutrition.*
 [FR Doc. 95-23776 Filed 9-25-95; 8:45 am]
BILLING CODE 4160-01-F

21 CFR Part 453
[Docket No. 95N-0081]

Antibiotic Drugs; Clindamycin Phosphate Vaginal Cream

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to include accepted standards for a new antibiotic drug, clindamycin phosphate vaginal cream. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective October 26, 1995; written comments, notice of participation, and request for a hearing by October 26, 1995; data, information, and analyses to justify a hearing by November 27, 1995.

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

FOR FURTHER INFORMATION CONTACT: James M. Timper, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6714.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new antibiotic drug, clindamycin phosphate vaginal cream. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended in part 453 (21 CFR part 453) to provide for the inclusion of accepted standards for this product.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because, when effective, it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, is effective October 26, 1995. However, interested persons may, on or before October 26, 1995, submit written comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before October 26, 1995, a written notice of participation and request for a hearing, and (2) on or before November 27, 1995, the data, information, and