31141) as being a component of the stabilizer, phosphorous acid, cyclic butylphenyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester. The correct identity of the stabilizer is phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester and is used throughout this final rule.

FDA has evaluated the data in the petition and other relevant material. 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 § 178.2010 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 § 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 January 29, 1997, 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).

§ 178.2010 [Amended]

2. Section 178.2010 *Antioxidants and/or stabilizers for polymers* is amended in the table in paragraph (b) in the entry for ''Phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester (CAS Reg. No. 161717–32–4'' by adding the phrase '', which may contain not more than 1 percent by weight of triisopropanolamine (CAS Reg. No. 122–20–3)'' before the period.

Dated: December 19, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–33099 Filed 12–27–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 201

[Docket No. 92N–0165]

Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Revision of ''Pediatric Use'' Subsection in the Labeling; Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA) is extending the compliance date of a final rule, that published in the Federal Register of December 13, 1994. The document revised the ''Pediatric use'' subsection of the professional labeling requirements for prescription drugs. This final rule extends to April 7, 1997, the date for submission of supplemental applications to comply with the new regulation for those manufacturers who notify FDA in writing by January 29, 1997 of their intent to submit a supplement. The agency is taking this action in response to a request for an extension of the compliance date.

EFFECTIVE DATE: December 30, 1996

FOR FURTHER INFORMATION CONTACT: Erica L. Keys, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 13, 1994 (59 FR 64240), FDA published a final rule that amended its regulations governing the content and format of labeling for human prescription drug products. The regulation revised the ''Pediatric use'' subsection of the professional labeling requirements for prescription drugs (21 CFR 201.57(f)(9)) to provide for the inclusion of more complete information about the use of a drug in the pediatric population (ages birth to 16 years). The regulation requires sponsors to reexamine existing data to determine whether the ''Pediatric use'' subsection of the labeling can be modified based on adequate and well-controlled studies in adults and other information supporting pediatric use, and, if appropriate, submit a supplemental application to comply with the new requirements by December 13, 1996. The final regulation gave manufacturers 2 years in which to submit supplements, in response to comments requesting that FDA extend the 1–year implementation period originally proposed.

On November 6, 1996, FDA sent a letter to 250 manufacturers asking them to notify the agency whether and when they intended to file supplements. FDA has received responses from only 40 manufacturers. On November 20, 1996, the Pharmaceutical Research and Manufacturers of America (PhRMA) requested that FDA extend the compliance date of the final rule because some of their members with large numbers of products had encountered unexpected problems in gathering the required information.

The absence of adequate pediatric labeling continues to present a significant public health issue and the level of response to the December 13, 1994, final rule is cause for concern. To

identify appropriate next steps to address this issue, it is essential that FDA identify the number of supplements that will be filed. Therefore, FDA is extending the compliance date under the following condition. If a manufacturer notifies FDA in writing by January 29, 1997, of their intent to submit a supplement, the agency will not consider the manufacturer's supplement to be late if it is received by April 7, 1997.

Because this action only extends the compliance date, FDA finds that there is good cause to dispense with a notice of proposed rulemaking, under 5 U.S.C. 553(b)(3)(B), as impracticable and unnecessary and is publishing this revision as a final rule effective December 30, 1996.

Dated: December 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–33098 Filed 12–27–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR PARTS 1301 and 1311

[DEA Number 140R]

RIN NUMBER 1117–AA34

Registration and Reregistration Application Fees

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule; remanded for further notice and comment.

SUMMARY: On October 6, 1992, Congress passed the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993, Pub. L. No. 102–395, 106 Stat. 1828 (1992) (codified at 21 U.S.C. 886a) (Act). In section 886a(3) of this Act, Congress directed that ''fees charged by the DEA under its Diversion Control Program (DCP) shall be set at a level that ensures the recovery of the full costs of operating the various aspects of the (diversion control) program.'' On December 18, 1992, DEA published its proposal to adjust the existing registration fee schedule. 57 FR 60,148. After notice and comment, DEA published a Final Rule on March 22, 1993, setting the new registration fees. 58 FR 15,272.

Following publication of the final rule, a complaint was filed by the American Medical Association (AMA) and others in the United States District Court for the District of Columbia. On July 5, 1994, the district court issued its final order granting the government's motion for summary judgment, and thus disposed of all claims with respect to all parties. *American Medical Association* v. *Reno,* 857 F. Supp. 80 (D.D.C. 1994). The AMA appealed. On June 27, 1995, the United States Court of Appeals for the District of Columbia Circuit issued its decision holding that DEA's rulemaking was inadequate and that the rule must be remanded, without being vacated, to the DEA for further proceedings in which DEA provides both an opportunity for meaningful notice and comment on, and an explanation of, the components of the diversion control program. 57 F.3d 1129 (D.C. Cir. 1995) On August 29, 1995, the United States Court of Appeals for the District of Columbia Circuit remanded this action to the district court with instructions. On November 22, 1995, the District Court remanded the matter to DEA for proceedings consistent with the opinion of the United States Court of Appeals for the District of Columbia Circuit. This document responds to that requirement and provides a description of the components of the fee-funded diversion control program.

DATES: Comments and objections must be submitted on or before March 31, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: The Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993 (Pub. L. 102–395) required that DEA recover the costs associated with the DCP through fees charged by DEA under that program. Therefore, DEA published a notice of proposed rulemaking (NPRM) in the Federal Register on December 18, 1992 (57 FR 60148) proposing to amend the fees set forth in Title 21, Code of Federal Regulations (21 CFR), §§ 1301.11 and 1311.11. On March 22, 1993, following notice and comment, DEA published a final rule in the Federal Register amending the fees.

DEA's rulemaking was challenged in court, in part on the grounds that it failed to provide adequate notice or explanation of the costs and scope of the DCP to be funded through the fees. While the United States District Court upheld the rule, on appeal, the United States Court of Appeals, District of Columbia Circuit decided on August 29, 1995, that the rulemaking was to be remanded, without being vacated, to DEA in order to identify the components of the fee-funded DCP and provide a brief explanation of why DEA deemed each component to be part of that program. Such description was to provide the opportunity for meaningful notice and comment regarding the established fee. *AMA, et al.* v. *Janet Reno, Attorney General, et al.,* 57 F.3d 1129 (D.C. Cir. 1995). In response to the decision of the court, the following explanation of the various components of the DCP is provided. Since the court did not vacate the final rule, DEA is not republishing either the original NPRM or final rule. Persons seeking further information regarding those notices should see the December 18, 1992 issue of the Federal Register (57 FR 60148) for the NPRM and the March 22, 1993 issue of the Federal Register (58 FR 15272) for the final rule.

Background of The Budget Item ''Diversion Control Program''

The Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91–513, commonly known as the Controlled Substances Act and the Controlled Substances Import and Export Act (CSA)), established the current Federal authority and programs to control the manufacture, distribution, importation, exportation and dispensing of ''controlled substances'' and to prevent the diversion of such substances from legitimate medical, scientific, research, and industrial channels into the illicit traffic. The CSA established a system of scheduling of substances, registration of legitimate handlers, production quotas, dispensing and distribution controls, record-keeping and reporting, import/export provisions, and penalties for violations of the CSA. It also mandated administrative and enforcement provisions, and cooperative efforts with state and local authorities. Additionally, as discussed in the later section regarding international activities, the United States has obligations under the United Nations Single Convention on Narcotic Drugs, 1961 (1961 Convention), and the Convention on Psychotropic Substances, 1971 (1971 Convention) (referred to collectively as the international treaties), to which it is a party, with respect to international control and cooperation to prevent the diversion of controlled substances. The CSA programs relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances are the domestic mechanism for implementing these treaty provisions. Over the past 25 years, the CSA has