

S. 23rd St., Arlington, VA 22202. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of phosphorous acid, cyclic neopentetetrayl bis(2,6-di-tert-butyl-4-methylphenyl) ester for use at levels not to exceed 0.15 percent by weight in polyolefins complying with § 177.1520 Olefin polymers (21 CFR 177.1520).

The agency has determined under 21 CFR 25.32(l) 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.

Dated: July 2, 1999

Alan M. Rulis

Director of Premarket Approval, Center for Food Safety and Applied Nutrition
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F-2534]

Ciba Specialty Chemicals Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba Specialty Chemicals Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of di(*n*-octyl)phosphite as an extreme pressure-antiwear adjuvant for lubricants intended for incidental contact with food.

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: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4683) has been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., P.O. Box 2005, Tarrytown, NY 10591-9005. The petition proposes to amend the food additive regulations in § 178.3570 *Lubricants with incidental food contact* (21 CFR 178.3570) to provide for the

safe use of di(*n*-octyl)phosphite as an extreme pressure-antiwear adjuvant for lubricants intended for incidental contact with food.

The agency has determined under 21 CFR 25.32(j) that this action is of the 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.

Dated: July 20, 1999.

Laura M. Tarantino,

Deputy Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 92P-0274 and 97P-0437]

Determination That Bendectin Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the drug product Bendectin, a tablet composed of pyroxidine hydrochloride, 10 milligram (mg), and doxylamine succinate, 10 mg, for the prevention of nausea during pregnancy was not withdrawn from sale for reasons of safety or effectiveness. This determination will permit FDA to approve abbreviated new drug applications (ANDA's) for the combination product pyroxidine hydrochloride, 10 mg, and doxylamine succinate, 10 mg, tablets.

FOR FURTHER INFORMATION CONTACT:

Andrea C. Masciale, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984 Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of approved innovator drug products under an ANDA procedure. ANDA sponsors generally must show that the drug for which they are seeking approval contains the same active ingredient in the same strength and

dosage form as the "listed drug," which is a drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's are not required to repeat the extensive clinical testing necessary to gain approval of an NDA. The only data from investigations required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Although they are technically drugs that should be listed under section 505(j)(7) of the act, certain drug products, including Bendectin, that were approved for safety and effectiveness but were no longer marketed on September 24, 1984, are not included in the Orange Book. In implementing the 1984 amendments, FDA decided not to retrospectively review products withdrawn from the market prior to the passage of the amendments. Rather, the agency decided to determine whether such drugs were withdrawn from the market for safety or effectiveness reasons on a case-by-case basis. A person interested in obtaining marketing approval for such a drug product through the ANDA process must petition the agency for a determination (21 CFR 314.122(d)).

Under FDA's regulations, drugs are withdrawn from the list if the agency withdraws or the Secretary of Health and Human Services suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). FDA must make a determination as to whether a listed drug was withdrawn for reasons of safety or effectiveness when a person petitions for such a determination (§ 314.161(a)(3) (21 CFR 314.161(a)(3))). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1)). FDA may not approve an ANDA that does not refer to a listed drug.

Bendectin is the subject of approved NDA 10-598, currently held by Hoechst Marion Roussel, Inc. (HMR). In 1956, FDA approved the NDA for Bendectin tablets for use in the prevention of