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 July 28, 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 objection 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
* * *	* * * *
2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5-hexyloxy)phenol (CAS Reg. No. 147315–50–2).	For use only 1. At levels not to exceed 0.5 percent by weight of polycarbonate resins complying with § 177.1580 of this chapter. 2. At levels not to exceed 0.5 percent by weight of polyester elastomers complying with § 177.1590 of this chapter.
* * *	* * * *

Dated: June 16, 1997.

L. Robert Lake,

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

[FR Doc. 97–16794 Filed 6–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F–0062]

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 expanded safe use of triisopropanolamine as a component of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester, a stabilizer for olefin polymers intended for use in contact with food. This action is in response to a petition filed by General Electric Co.

DATES: Effective June 27, 1997; written objections and requests for a hearing by July 28, 1997.

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

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 February 28, 1997 (62 FR 9197), FDA announced that a food additive petition (FAP 7B4535) had been filed by General Electric Co., One Lexan Lane, Mt. Vernon, IN 47620–9364. The petition proposed 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 triisopropanolamine as a component of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester, a stabilizer for olefin polymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and (3) 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 July 28, 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).

2. Section 178.2010 is amended in the table in paragraph (b) by revising the entry for ''Phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester'' under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * *
Phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester (CAS Reg. No. 161717–32–4), which may contain not more than 1 percent by weight of triisopropanolamine (CAS Reg. No. 122–20–3).	For use only: 1. At levels not to exceed 0.2 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, or 1.3, and items 2.1, 2.2, or 2.3 (where the density of these polymers is not less than 0.94 gram per cubic centimeter), and items 3.1 or 3.2, provided that the finished polymer contacts foods of types I, II, and VI–B as described in Table 1 of § 176.170(c) of this chapter only under conditions of use B, C, D, E, F, G, and H as described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, or 1.3, that contact food of types III, IV, V, VI–A, VI–C, VII, VIII, and IX as described in Table 1 of § 176.170(c) of this chapter, only under conditions of use C, D, E, F, and G as described in Table 2 of § 176.170(c) of this chapter. 3. At levels not to exceed 0.1 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter, items 3.1 or 3.2, having a density less than 0.94 grams per cubic centimeter, in contact with food only of types III, IV, V, VI–A, VI–C, VII, VIII, and IX and under conditions of use C, D, E, F, and G as described in Tables 1 and 2 of § 176.170(c) of this chapter; provided that the food-contact surface does not exceed 0.003 inch (0.076 mm) in thickness.
* * *	* * * *

Dated: June 16, 1997.

L. Robert Lake,

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

[FR Doc. 97–16795 Filed 6–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Animal Drugs, Feeds, and Related Products; Selegiline Hydrochloride Tablet

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Deprenyl Animal Health, Inc. The NADA provides for oral use of selegiline hydrochloride tablets for dogs for the control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism.

EFFECTIVE DATE: June 27, 1997.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center For Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Deprenyl Animal Health, Inc., 7101 College Blvd., suite 580, Overland Park, KS 66210, filed NADA 141–080, which provides for oral use of Anipryl® (selegiline hydrochloride) tablets for dogs for the control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of May 30, 1997, and the regulations are amended by adding new 21 CFR 520.2098 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Deprenyl Animal Health, Inc., has not previously been listed in the animal drug regulations as the sponsor of an approved application. At this time, 21 CFR 510.600(c) is amended to add listings for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. to 4 p.m., Monday to Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning May 30, 1997, because no active ingredient of the drug, including any ester or salt of the active ingredient, has been approved in any other application.

FDA has carefully considered the potential environmental effects of this action and has concluded that this action will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA'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 (see above).

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Deprenyl Animal Health, Inc.''and in the table in paragraph (c)(2) by numerically adding a new entry for ''063248'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
Deprenyl Animal Health, Inc., 7101 College Blvd., suite 580, Overland Park., KS 66210.	063248
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
063248	Deprenyl Animal Health, Inc., 7101 College Blvd., suite 580, Overland Park, KS 66210.
* * *	* * * *