Dated: June 16, 1997.

L. Robert Lake,

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

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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.
* * *	* * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

4. New § 520.2098 is added to read as follows:

§ 520.2098 Selegiline hydrochloride tablets.

(a) *Specifications.* Each tablet contains either 2, 5, 10, 15, or 30 milligrams of selegiline hydrochloride.

(b) *Sponsor.* See No. 063248 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*— (1) *Dosage.* 1 milligram per kilogram (0.45 milligram per pound) of body weight.

(2) *Indications for use.* For control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism.

(3) *Limitations.* Administer orally once daily. If no improvement in clinical signs or physical examination findings after 2 months of therapy, increase dose to a maximum of 2 milligrams per kilogram once daily. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: June 16, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–16791 Filed 6–26–97; 8:45 am]

BILLING CODE 4160–01–F

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Exchange Visitor Program

AGENCY: United States Information Agency.

ACTION: Interim final rule with request for comment.

SUMMARY: The Agency is amending existing regulations in order to enhance the Agency's oversight of au pair programs. These amendments provide additional specificity to existing regulations that will facilitate consistent compliance with programmatic requirements. Specifically, these amendments will further define the selection and screening requirements for au pair participants and require that the participant attend rather than merely enroll for six hours of academic credit. Further, the number of hours an au pair may provide child care services is limited to no more than 10 hours per day and forty-five in any given week.

DATES: This rule is effective September 1, 1997. Written comments regarding this rule will be accepted July 28, 1997.

ADDRESSES: Comments regarding this rule must be presented in duplicate and addressed as follows: United States Information Agency, Office of the General Counsel, Rulemaking 210, 301 4th Street, SW., Washington, DC 20547.

FOR FURTHER INFORMATION CONTACT: Exchange Visitor Program Services, Program Designation Branch, United States Information Agency, 301 4th Street, SW., Washington, DC 20547; Telephone (202) 401–9810.

SUPPLEMENTARY INFORMATION: In consultation with the eight sponsors designated by the Agency to conduct au pair programs, the Agency is amending the regulations that govern the administration of au pair programs. These regulations were adopted February 15, 1995 (60 FR 8547) following an extensive public comment period that generated more than 3,000 public comments. As is often the case in the promulgation of regulations governing a program-based activity such as the au pair program, the need for further sepcificity regarding regulatory implementation and compliance has arisen. Accordingly, the Agency has worked with the eight designated sponsors to amend these regulations to provide such additional specificity.

First, the Agency is amending the existing requirement set forth at 22 CFR 514.31(c)(3) to ensure that au pair participants attend rather than merely enroll for six hours of academic credit at an institution of higher education. The requirement that au pair participants pursue academic course work is considered to be the foundation underlying the au pair program. This requirement ensures that the young adults participating in this program are engaged in activities other than child care and provides the opportunity for the au pair to interact with persons their own age and gain further insight regarding the United States and its people.

Secondly, the Agency is amending the requirements governing the selection and placement of au pair participants set forth at 22 CFR 514.31(d) and (h) in order to enhance the ability of an au pair host family to more actively participate in the selection of the au pair participant that the family will host. A report by the organizational representative interviewing the au pair participant will be provided to the host family. With this information and the references also provided to the host family, such family may develop a more informed opinion regarding the au pair participant's potential compatibility with the family. The Agency anticipates that host families may contact the listed references as they deem appropriate. Further, amendment of this regulation will more clearly define the requirement that an au pair participant successfully pass a personality profile. This amendment will require that the au pair successfully complete a personality profile based on a psychometric test that measures the differences in characteristics among applicants against those characteristics considered most important to successfully participate in the au pair program.

In concert with these changes that will assist the host family in selecting an au pair, the Agency is also introducing requirements set forth at 22 CFR 514.31 (f) and (i) that will require au pair sponsors to provide all host families and au pair participants with a statement from the Agency regarding the au pair program itself. The Agency believes that the few complaints that arise from this program are often related to the lack of a full and complete understanding of the program by either the host family or the au pair. By providing a statement from the Agency that sets forth an overview of the program, the Agency is of the opinion that many conflicts between the au pair, the sponsoring organization, and the au pair will be avoided.

The Agency has also reviewed the training and experience requirements for au pair participants and amends 22 CFR 514.31 (e), (f) and (g) to enhance and clarify such requirements. To this end, au pair participants that will care for children under the age of two must have no less than 200 hours of documented infant child care experience. This experience must involve the direct care and supervision of infant children. Further, au pairs will receive, prior to departure from their home country, a pre-departure package that both clearly describes their prospective child care responsibilities and enumerates unacceptable behavior. Au pairs will continue to receive not less than eight hours of child safety instruction and not less than twenty-four hours of child development instruction. The Agency is, however, amending this requirement to specifically require that no less than four hours of the child safety instruction be infant related and that not less than four of the twenty-four hours of child development instruction be devoted to training for the care of children under the age of two. Child safety instruction shall be provided by the American Red