NW, Mail Stop 5–6, Washington, DC 20549.

I. Supplementary Information

Under section 203A of the Investment Advisers Act of 1940 (''Advisers Act''), the Commission has regulatory responsibility for an investment adviser that has at least $25 million of assets under management or advises a registered investment company. The Commission also has responsibility for an adviser that has less than $25 million of assets under management, if its principal office and place of business is in a state that has not enacted investment adviser legislation.[1] An adviser with its principal office in one of those states must indicate its eligibility for Commission registration on Schedule I of Form ADV.[2]

Colorado and Iowa recently passed investment adviser statutes, which became effective on January 1, 1999. An adviser that has its principal office and place of business in Colorado or Iowa, therefore, may not register with the Commission unless it has at least $25 million of assets under management, advises an investment company, or qualifies for an exemption under rule 203A–2.[3] Last July, the Commission adopted certain amendments to Schedule I to Form ADV.[4] The Commission today is making additional technical changes to Schedule I and the Instructions to Schedule I to reflect enactment of the Colorado and Iowa legislation.

New advisers (*i.e.*, those advisers that are not currently registered with the Commission) that have their principal place of business in Colorado or Iowa that are not eligible for Commission registration (*e.g.*, because they do not have at least $25 million of assets under management) must now register with Colorado or Iowa.[5] Advisers currently registered with the Commission solely because their principal office and place of business is located in Colorado or Iowa must withdraw from Commission registration no later than 180 days after the end of their fiscal year.[6]

II. Certain Findings

Under the Administrative Procedure Act (''APA''), notice of proposed rulemaking is not required when the agency, for good cause, finds ''that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' [7] The Commission is making technical changes to Schedule I to Form ADV to accommodate new legislation in Colorado and Iowa. The Commission, therefore, finds that publishing the changes for comment is unnecessary.

Publication of a substantive rule not less than 30 days before its effective date is required by the APA except as otherwise provided by the agency for good cause.[8] For the same reasons described above with respect to notice and opportunity for comment, the Commission finds that there is good cause for making these technical changes effective on January 7, 1999.

List of Subjects in 17 CFR Part 279

Reporting and recordkeeping requirements; Securities.

Accordingly, 17 CFR part 279 is amended as follows:

PART 279—FORMS PRESCRIBED UNDER THE INVESTMENT ADVISERS ACT OF 1940

1. The authority citation for part 279 continues to read as follows:

Authority: The Investment Advisers Act of 1940, 15 U.S.C. 80b–1, *et seq.*

2. By amending Schedule I to Form ADV (referenced in § 279.1) to remove all references to ''Colorado'' and ''Iowa'' and by amending the Instructions to Schedule I to Form ADV (referenced in § 279.1) to remove references to ''Colorado'' and ''Iowa'' and to remove the second paragraph under ''Instruction 3.''

Note: The text of Schedule I to Form ADV (§ 279.1) does not and the corrections will not appear in the Code of Federal Regulations.

Dated: January 7, 1999.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–738 Filed 1–12–99; 8:45 am]

BILLING CODE 8010–01–U

[1] 15 U.S.C. 80b–3a.

[2] 17 CFR 279.1. Under rule 203–1 (17 CFR 275.203–1), an adviser must file Schedule I to Form ADV with its initial application for Commission registration, and under rule 204–1 (17 CFR 275.204–1), an adviser must file Schedule I to Form ADV with annual amendments to Form ADV.

[3] 17 CFR 275.203A–2.

[4] *See* Exemption for Investment Advisers Operating in Multiple States; Revisions to Rules Implementing Amendments to the Investment Advisers Act of 1940; Investment Advisers with Principal Offices and Places of Business in Colorado or Iowa, Investment Advisers Act Release No. 1733 (July 17, 1998) (63 FR 39708 (July 24, 1998)).

[5] In addition, advisers ineligible for Commission registration that have their principal office in Colorado or Iowa may be required to register in another state, if they have six or more clients that are residents of that state or have a place of business in that state. *See* Advisers Act section 222(d) (15 U.S.C. 80b–22(d)).

[6] Under rule 204–1(a) (17 CFR 275.204–1), an adviser is required to file its annual amendment to Form ADV within 90 days of the end of its fiscal year. Under rule 203A–1(c) (17 CFR 275.203A–1(c)), an adviser that is no longer eligible for Commission registration must withdraw from Commission registration within 90 days from the date the adviser was required to file its amended Form ADV. *See also* Schedule I to Form ADV, Instruction 6 (17 CFR 279.1).

[7] 5 U.S.C. 553(b).

[8] 5 U.S.C. 553(d).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Selegiline Hydrochloride Tablets

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 supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for oral veterinary prescription use of selegiline hydrochloride tablets for dogs for the control of clinical signs associated with cognitive dysfunction syndrome.

EFFECTIVE DATE: January 13, 1999.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center For Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 141–080 that provides for oral veterinary prescription use of Anipryl® (selegiline hydrochloride) tablets for dogs for the control of clinical signs associated with canine cognitive dysfunction syndrome. The product is approved for the control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism. The supplement is approved as of December 10, 1998, and the regulations are amended by revising 21 CFR 520.2098 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 supplemental application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday

through Friday, except on Federal holidays.

Under 21 U.S.C. 360b(c)(2)(F)(iii), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning December 10, 1998, because the supplement contains substantial evidence of the effectiveness of the drug involved or any studies of animal safety required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to veterinary prescription use of the drug in dogs for the control of clinical signs associated with cognitive dysfunction syndrome.

The agency has determined under 21 CFR 25.33(d)(1) 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.

List of Subjects in 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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 360b.

2. Section 520.2098 is amended by redesignating paragraphs (d)(2) and (d)(3) as paragraphs (d)(1)(i) and (d)(1)(ii), respectively, and by adding paragraph (d)(2) to read as follows:

§ 520.2098 Selegiline hydrochloride tablets.

* * * * *

(d) *Conditions of use.* * * *

(2) *Dosage.* 0.5 to 1.0 milligram per kilogram of body weight once daily.

(i) *Indications for use.* For the control of clinical signs associated with canine cognitive dysfunction syndrome.

(ii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: January 6, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–739 Filed 1–12–99; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 4, 5, 7, 13, and 19

[TD ATF–406 Re: Notice No. 815 and Notice No. 819]

RIN: 1512–AB34

Procedures for the Issuance, Denial, and Revocation of Certificates of Label Approval, Certificates of Exemption From Label Approval, and Distinctive Liquor Bottle Approvals (93F–029P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is issuing regulations setting forth the procedures for the issuance, denial, and revocation of certificates of label approval (COLAs), certificates of exemption from label approval, and distinctive liquor bottle approvals. The denial and revocation regulations are new, whereas the issuance regulations merely amend current regulations. The new regulations also codify procedures for administratively appealing the denial or revocation of certificates of label approval, exemptions from label approval, or distinctive liquor bottle approvals.

DATES: These regulations are effective March 15, 1999.

ADDRESSES: Copies of the proposed regulation and written comments are available for public inspection during normal business hours at: ATF Reading Room, Office of Public Affairs and Disclosure, Room 6480, 650 Massachusetts Avenue, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Edward A. Reisman, Jr., Product Compliance Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW, Washington, DC 20226 (202–927–8140).

SUPPLEMENTARY INFORMATION:

Background

The Federal Alcohol Administration (FAA) Act, 27 U.S.C. 205(e), provides ATF, as the delegate of the Secretary of the Treasury, with authority to promulgate regulations with respect to the bottling, packaging, and labeling of distilled spirits, wine, and malt beverages in order to prohibit deception of the consumer, and provide the consumer with adequate information as to the identity and quality of the product.

In order to carry out such requirements, domestic bottlers and producers are prohibited from bottling distilled spirits, wines, or malt beverages, and importers are prohibited from removing bottled distilled spirits, wines, or malt beverages from customs custody unless they have in their possession a certificate of label approval covering such products, ''issued by the Secretary in such manner and form as he shall by regulations prescribe.'' 27 U.S.C. 205(e). The law provides an exemption from these requirements for products that are not to be sold, offered for sale, or shipped or delivered for shipment, or otherwise introduced, in interstate or foreign commerce.

The regulations implementing these statutory provisions provide that no person shall bottle or pack wine, distilled spirits, or malt beverages unless application is made to the Director and an approved certificate of label approval, ATF Form 5100.31, is issued. 27 CFR 4.50(a), 5.55(a), and 7.41. The regulations also provide that no bottled wines, distilled spirits, or malt beverages shall be released from customs custody for consumption unless an approved certificate of label approval, ATF Form 5100.31, is deposited with the appropriate customs officer at the port of entry. 27 CFR 4.40(a), 5.51(a), and 7.31(a).

A bottler of wine or distilled spirits who can show to the satisfaction of the Director that the product is not to be sold, offered for sale, or shipped or delivered for shipment or otherwise introduced in interstate or foreign commerce, must make application for exemption from the labeling requirements of the FAA Act on ATF Form 5100.31 in accordance with the instructions on the form. If the application is approved, a certificate of exemption from label approval will be issued on the same form. 27 CFR 4.50(b) and 5.55(b). Certificates of exemption from label approval are not issued for malt beverages.

Finally, the ATF Form 5100.31 is also used to obtain approval for distinctive liquor bottles, pursuant to the regulations appearing at 27 CFR 19.633(a). ATF's authority to regulate liquor bottles is derived from section 5301 of the Internal Revenue Code of 1986, 26 U.S.C. 5301. However, the approval of a distinctive liquor bottle also includes the approval of the label on that bottle, pursuant to the FAA Act.

Revocation of COLAs

ATF reviews approximately 60,000 applications for certificates of label approval, exemptions from label approval, and distinctive liquor bottle