

approval does not qualify for an exclusivity period because reports of new clinical or field investigations (other than bioequivalence or residue studies) and, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) essential to the approvals and conducted or sponsored by the applicant were not required.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects

##### 21 CFR Part 522

Animal Drugs.

##### 21 CFR Part 556

Animal drugs, Foods.

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 522 and 556 are amended as follows:

#### PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

2. Section 522.820 is revised to read as follows:

##### § 522.820 Erythromycin Injection.

(a) *Sponsor.* See 050604 in § 510.600(c) of this chapter.

(b) *NAS/NRC status.* The conditions of use have been reviewed by NAS/NRC and found effective.

(c) *Dogs and cats.*—(1) *Specifications.* Each milliliter of polyethylene glycol vehicle contains 100 milligrams of erythromycin base with 2 percent butyl aminobenzoate.

(2) *Conditions of use*—(i) *Amount.* 3 to 5 milligrams per pound of body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use*—(A) *Dogs.* For the treatment of bacterial pneumonia, upper respiratory infections (tonsillitis, bronchitis, tracheitis, pharyngitis, pleurisy), endometritis and metritis, and bacterial wound infections caused by

*Staphylococcus* spp., *Streptococcus* spp., and *Corynebacterium* spp., sensitive to erythromycin.

(B) *Cats.* For the treatment of bacterial pneumonia, upper respiratory infections (rhinitis, bronchitis), secondary infections associated with panleukopenia, and bacterial wound infections caused by *Staphylococcus* spp. and *Streptococcus* spp., susceptible to erythromycin.

(iii) *Limitations.* Administer by deep intramuscular injection into the heavy muscles of the neck and limbs. Do not administer intravenously or intraperitoneally. Avoid subcutaneous use. Do not administer from moist or wet syringe. As with all antibiotics, appropriate in vitro culturing and susceptibility testing of samples taken before treatment should be conducted. Do not administer in conjunction with penicillin. As with all antibiotics, excessive continuous use may result in an overgrowth of nonsusceptible organisms. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Cattle.*—(1) *Specifications.* Each milliliter of nonaqueous, buffered, alcohol base sterile solution contains 200 milligrams of erythromycin base.

(2) *Related tolerances.* See § 556.230 of this chapter.

(3) *Conditions of use*—(i) *Amount.* 4 milligrams of erythromycin base per pound of body weight once daily for up to 5 days.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* susceptible to erythromycin.

(iii) *Limitations.* For intramuscular use only. Do not use in female dairy cattle over 20 months of age. Do not slaughter treated animals within 6 days of last treatment. To avoid excess trim, do not slaughter within 21 days of last injection.

#### PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** Sec. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. Section 556.230 is amended by revising paragraphs (a) and (b) to read as follows:

##### § 556.230 Erythromycin.

\* \* \* \* \*

(a) 0.1 part per million in uncooked edible tissues of beef cattle and swine.

(b) Zero in milk.

\* \* \* \* \*

Dated: August 4, 1993.

Richard H. Teske,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 93-19739 Filed 8-17-93; 8:45 am]

BILLING CODE 4160-01-F

#### DEPARTMENT OF JUSTICE

##### Drug Enforcement Administration

##### 21 CFR Part 1308

#### Schedules of Controlled Substances; Transfer of Levo-alphaacetylmethadol From Schedule I into Schedule II

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

**SUMMARY:** With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) transfers the Schedule I narcotic, levo-alphaacetylmethadol (LAAM), into Schedule II of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule II will be applicable to the manufacture, distribution, importation and exportation of LAAM. Additionally, the use of LAAM for the treatment of narcotic addiction will be subject to compliance with the requirements of the Narcotic Addict Treatment Act of 1974 and regulations concerning narcotic treatment programs.

**EFFECTIVE DATE:** August 18, 1993, except for those individuals who are currently registered with DEA and possess LAAM shall take inventory and meet recordkeeping requirements on or before September 17, 1993.

**FOR FURTHER INFORMATION CONTACT:** Howard McClain, Jr., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, telephone: (202) 307-7183.

**SUPPLEMENTARY INFORMATION:** LAAM is a synthetic opioid agonist. It will be marketed under the trade name of ORLAAM for the treatment of narcotic addiction. In a letter dated March 12, 1993, the Assistant Secretary for Health, acting on behalf of the Secretary of the Department of Health and Human Services, recommended to the Administrator of the DEA that LAAM be transferred from Schedule I into Schedule II of the CSA pending approval of a New Drug Application (NDA) for the use of LAAM in the

treatment of narcotic addiction. The Administrator of the DEA, in an April 28, 1993 Federal Register notice (58 FR 25790), proposed to transfer LAAM into Schedule II of the CSA if and when the Food and Drug Administration (FDA) approved an NDA for LAAM. This notice provided an opportunity for all interested persons to submit their comments, objections or requests for a hearing in writing on the proposed transfer of LAAM from Schedule I into Schedule II. Comments to the Administrator of the DEA were to be received on or before May 28, 1993. The Administrator received one comment supporting the transfer of LAAM into Schedule II but received no objections or requests for a hearing regarding this proposal. The FDA has notified the DEA that LAAM is safe and effective for use in the treatment of narcotic addiction as recommended in the approved labeling. The NDA for LAAM was approved on July 9, 1993.

Based on the information gathered and reviewed by the DEA, the scientific and medical evaluation and scheduling recommendation of the Assistant Secretary for Health, and the FDA's approval of the NDA for LAAM, the Administrator of the DEA, pursuant to the provisions of 21 U.S.C. 811 (a) and (b) and 812(b), finds that:

- (1) LAAM has a high potential for abuse;
- (2) LAAM has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and
- (3) Abuse of LAAM may lead to severe psychological or physical dependence.

The above findings are consistent with the placement of LAAM into Schedule II of the CSA. This transfer will apply to the *levo* isomer of alphacetylmethadol while all other isomers of alphacetylmethadol will remain in Schedule I.

The following regulations are effective with respect to LAAM on August 18, 1993, except for those individuals who are currently registered with DEA in accordance with part 1301 or 1311 of title 21 of the Code of Federal Regulations and possess LAAM shall take inventory and meet recordkeeping requirements on or before September 17, 1993:

1. **Registration.** Any person who manufactures, distributes, dispenses, delivers, imports or exports LAAM, or who conducts a narcotic treatment program using LAAM, or who engages in research or conducts instructional activities with LAAM, or who proposes to engage in such activities, must be registered to conduct such activities in

accordance with parts 1301 and 1311 of title 21 of the Code of Federal Regulations.

2. **Security.** LAAM must be manufactured, distributed and stored in accordance with §§ 1301.71–1301.76 of title 21 of the Code of Federal Regulations.

3. **Labeling and packaging.** All labels and labeling for commercial containers of LAAM must comply with the requirements of §§ 1302.03–1302.05, 1302.07, and 1302.08 of title 21 of the Code of Federal Regulations.

4. **Quotas.** All persons required to obtain quotas for LAAM shall submit applications pursuant to 21 CFR 1303.11, 1303.12, and 1303.22.

5. **Inventory.** Every registrant required to keep records and who possesses any quantity of LAAM shall take an inventory pursuant to §§ 1304.11–1304.19 of title 21 of the Code of Federal Regulations.

6. **Records.** All registrants required to keep records pursuant to §§ 1304.21–1304.29 of title 21 of the Code of Federal Regulations shall do so regarding LAAM.

7. **Reports.** All registrants required to submit reports pursuant to §§ 1304.34–1304.37 of title 21 of the Code of Federal Regulations shall do so regarding LAAM.

8. **Order forms.** All registrants involved in the procurement or distribution of LAAM shall comply with the order form requirements of part 1305 of title 21 of the Code of Federal Regulations.

9. **Prescriptions.** All prescriptions for products containing LAAM shall comply with §§ 1306.01–1306.07 and §§ 1306.11–1306.15 of title 21 of the Code of Federal Regulations.

10. **Importation and exportation.** All importation and exportation of LAAM shall be in compliance with part 1312 of title 21 of the Code of Federal Regulations.

11. **Criminal liability.** Any activity with respect to LAAM not authorized by, or in violation of the CSA or the Controlled Substances Import and Export Act shall be unlawful. The applicable penalties before August 18, 1993, shall be those of a Schedule I narcotic controlled substance. On August 18, 1993 LAAM, for the purposes of criminal liability, shall be treated as a Schedule II narcotic substance.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the transfer of LAAM will have no significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96–354). Many

of the regulatory requirements imposed on Schedule II substances are similar to those imposed on Schedule I substances. Additionally, substances in Schedule II may be used in medical treatment in the United States and this action will allow the marketing of the product ORLAAM that has been approved by FDA.

This action has been analyzed in accordance with the principles and criteria contained in E.O. 12612, and it has been determined that this matter does not have sufficient federalism implications to require the preparation of a Federalism Assessment.

In accordance with the provisions of 21 U.S.C. 811(a), this ruling to transfer LAAM from Schedule I to Schedule II is a formal rule making "on the record after opportunity for hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and as such have been exempted from the consultation requirements for Executive Order 12291 (46 FR 13193).

#### List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs, Reporting and Record keeping requirements.

Under the authority vested in the Attorney General (21 U.S.C. 811(a)) and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100), the Administrator hereby rules that 21 CFR part 1308 be revised as follows:

#### PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.11 is amended by revising paragraph (b)(4) to read as follows:

#### § 1308.11 Schedule I.

\* \* \* \* \*

(b) \* \* \*

(4) Alphacetylmethadol (except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM)—9603

\* \* \* \* \*

3. Section 1308.12 is amended by redesignating the existing paragraphs (c)(11) through (c)(25) as (c)(12) through (c)(26) respectively and adding a new paragraph (c)(11) to read as follows:

#### § 1308.12 Schedule II.

\* \* \* \* \*

(c) \* \* \*

(11) Levo-alphacetylmethadol—9648

[Some other names: levo-alpha-acetylmetadon, levomethadon acetate, LAAM]

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Dated: August 11, 1993.

Robert C. Bonner,

Administrator of Drug Enforcement.

[FR Doc. 93-19818 Filed 8-17-93; 8:45 am]

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[T.D. 8483]

RIN 1545-AR06

#### Earnings and Profits of Regulated Investment Companies and Real Estate Investment Trusts

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final Regulations.

**SUMMARY:** This document contains final income tax regulations relating to regulated investment companies (RICs) and real estate investment trusts (REITs). The regulations provide guidance to RICs and REITs that have earnings and profits (E&P) accumulated by a corporation during a taxable year when the corporation was not taxable as a RIC or REIT. This guidance is needed to clarify the requirements for maintaining RIC or REIT status after a merger or other reorganization. The regulations also provide procedural guidance to REITs that distribute non-REIT E&P.

**DATES:** The effective date of these regulations is December 22, 1992.

These regulations apply to taxable years ending on or after December 22, 1992.

**FOR FURTHER INFORMATION CONTACT:**

Jonathan D. Silver, 202-622-3920 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

This document adds §§ 1.852-12 and 1.857-11 to the Income Tax Regulations (26 CFR part 1) under sections 852 and 857 of the Internal Revenue Code (Code).

On December 23, 1992, the Internal Revenue Service published a notice of proposed rulemaking in the *Federal Register* (57 FR 61017). One commentator submitted written comments concerning the proposed regulations and requested a public hearing. A public hearing on those comments was held on March 1, 1993.

### Explanation of Provisions

This document provides guidance to a RIC or REIT that has non-RIC or non-REIT E&P (that is, E&P that was accumulated by a corporation during a taxable year when the corporation was not taxable as a RIC or REIT). The regulations clarify that a company is not taxable as a RIC or REIT for a taxable year if it has non-RIC or non-REIT E&P at the close of the taxable year, even if the E&P was succeeded to in a reorganization.

The regulations prescribe identical rules for both RICs and REITs. Under the regulations, a RIC that succeeds to non-RIC E&P is generally required to distribute that E&P if the RIC is to continue to be taxable as a RIC. Similarly, a REIT that succeeds to non-REIT E&P is generally required to distribute that E&P if the REIT is to continue to be taxable as a REIT.

The one commentator on the proposed regulations questioned the scope of the regulations and argued that the statutory language of section 852(a)(2) of the Code is directed at a non-RIC that elects RIC status and not at a non-RIC that attains RIC status through a merger or other reorganization with an existing RIC. The commentator suggested that the E&P acquired by a RIC when it acquires a non-RIC through a merger or other reorganization is not "accumulated" for purposes of section 852(a)(2) of the Code since, under section 381(c)(2), the RIC succeeds to the E&P on the date of the reorganization. The commentator also suggested that, in enacting section 852(a)(2), Congress was concerned with operating companies that would sell their assets used in business, purchase investment assets, and then elect RIC status without distributing accumulated E&P. The commentator reasoned that Congress was not concerned with this happening through a merger of a non-RIC into a RIC because the continuity of business enterprise requirement for a reorganization would not be satisfied.

As asserted by the commentator, the legislative history of section 852(a)(2) of the Code indicates that Congress was concerned with operating companies that sold their assets, invested the proceeds in passive investment assets, and obtained conduit treatment without distributing the earnings from the operating activities. H.R. Rep. No. 432, 98th Cong., 2d Sess., pt. 2, at 1744 ff. (1984). There is no indication, however, that Congress intended to limit the application of the statute to that particular fact situation. The resulting statute clearly is broader than the transaction described in the legislative

history and applies to all non-RIC E&P, no matter what its source.

The same concerns arise no matter how the non-RIC E&P comes to be held by a RIC. For instance, a historic investment business may not elect RIC status without distributing its non-RIC E&P. There is no reason to distinguish between that transaction and one in which the same company merges into a RIC. Moreover, any interpretation of the statute that distinguishes between corporations electing RIC status and corporations reorganizing into RICs would result in inconsistent tax treatment based solely on the form of the transaction.

After consideration of the comments, the Service continues to believe that the regulations are supported by legislative history and accurately reflect congressional concern. Section 852(a)(2) of the Code was intended to require a RIC that had non-RIC E&P, from whatever source, to distribute that E&P as a prerequisite to the RIC being taxable under subchapter M, part I.

The legislative history of section 857(a)(3) of the Code indicates that section 857(a)(3) serves a purpose similar to that of section 852(a)(2): Congress did not want companies to be taxable as REITs if they had non-REIT E&P. S. Rep. No. 313, 99th Cong., 2d Sess. 769, 775 (1986). As with RICs, the same principles apply to non-REIT E&P, whether it is carried over when the company converts to REIT status or it is succeeded to when a REIT reorganizes with a corporation that is not taxable as a REIT.

Finally, the regulations retain the rule in the proposed regulations that distribution rules similar to those in section 852(e) are to apply to REITs. No comments were received on this portion of the proposed regulations.

### Special Analyses

It has been determined that these rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.