

for treating female equine genital tract infections and impaired fertility in addition to the existing approval for treating surface bacterial infections in dogs, cats, and horses. The application was filed by Biomed Laboratories.

EFFECTIVE DATE: December 28, 1982.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; 301-443-3420.

SUPPLEMENTARY INFORMATION: Biomed Laboratories, 4542 Denver St., Montclair, Calif. 91763, is sponsor for supplemental NADA 126-950 providing revised labeling for use of Fura-Vet (0.2 percent nitrofurazone solution) for treating female equine genital tract infections and impaired fertility. The firm has existing approval for use of the drug for treating surface bacterial infections in dogs, cats, and horses. The existing approval permits over-the-counter marketing of the drug, but addition of the genital tract and impaired fertility claims to a common label requires that the product now be restricted to veterinary prescription use. The nitrofurazone solution regulation provides that since all of the aforementioned conditions of use are NAS/NRC reviewed and found effective, applications for these uses need not include effectiveness data as specified by 21 CFR 514.111. The product is intended for topical use; therefore, the requirement for bioequivalency is waived under 21 CFR 320.22(b)(2). The application is approved, and the regulations are amended accordingly.

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. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

List of Subjects in 21 CFR Part 524

Animal drugs, topical.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 524 is amended in § 524.1580d by revising paragraph (b), to read as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

§ 524.1580d Nitrofurazone solution.

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(b) *Sponsor.* See 000857, 015562, 015579, and 051259 in § 510.600(c) of this chapter for use as in paragraph (d) (1) and (2) of this section.

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Effective date: December 28, 1982.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: December 20, 1982.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

(FR Doc. 82-34943 Filed 12-27-82; 8:45 am)

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Placement of Triazolam Into Schedule IV

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Acting Administrator of the Drug Enforcement Administration (DEA) to place the substance, triazolam, into Schedule IV of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This action is based on a finding that triazolam fits the statutory criteria for inclusion in Schedule IV of the CSA. As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV of the CSA will be applicable to the manufacturing, distribution, importation and exportation of triazolam.

EFFECTIVE DATE: December 28, 1982.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, D.C. 20537; telephone (202) 633-1366.

SUPPLEMENTARY INFORMATION: A proposed rule was published in the *Federal Register* on Wednesday, April 29, 1981, (46 FR 23953-4), proposing that triazolam be placed into Schedule IV of the CSA if and when the triazolam New Drug Application (NDA) receives final approval from the Food and Drug Administration (FDA). All persons were given until June 29, 1981, to submit any comments or objections in writing regarding this proposal. One comment was received from the American Society for Hospital Pharmacists (ASHP), which supported the placement of triazolam into Schedule IV. No other comments or objections were received in response to this proposal nor were there any requests for a hearing.

By letter dated November 22, 1982, the FDA notified DEA of the final NDA approval for triazolam contingent upon the announcement of a final scheduling decision in the *Federal Register*. This final rule fulfills that scheduling condition for triazolam.

Triazolam is a member of the benzodiazepine class of drugs. It is a central nervous system depressant and has been clinically evaluated as a hypnotic.

Relying on the scientific and medical evaluation and recommendation of the Acting Assistant Secretary for Health and based on his independent evaluation in accordance with the provisions of 21 U.S.C. 811(c), the Acting Administrator of the Drug Enforcement Administration, pursuant to the provisions of 21 U.S.C. 811(a) and 811(b), finds that:

(1) Based on information now available, triazolam has a low potential for abuse relative to the drugs or other substances listed in Schedule III;

(2) Triazolam has a currently acceptable medical use in treatment in the United States; and

(3) Abuse of triazolam may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

The above findings are consistent with the placement of triazolam into Schedule IV of the Controlled Substances Act. In order to avoid delays in the initial marketing of triazolam, the control of triazolam in Schedule IV will be effective on December 28, 1982. In the event this imposes special hardships on any registrant, the Drug Enforcement Administration will entertain any justified request for an extension of time to comply with the Schedule IV regulations. The applicable regulations are as follows:

1. **Registration.** Any person who manufactures, distributes, delivers, imports or exports triazolam, or who engages in research or conducts instructional activities with respect to this substance, 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.** Triazolam 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 triazolam must comply with the requirements of §§ 1302.03-1302.05 and 1302.08 of Title 21 of the Code of Federal Regulations.

4. **Inventory.** Every registrant required to keep records who possesses any quantity of triazolam shall take inventories, pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of triazolam on hand.

5. **Records.** All registrants required to keep records pursuant to §§ 1304.21-1304.27 of Title 21 of the Code of Federal Regulations shall do so regarding triazolam.

6. **Prescriptions.** All prescriptions for products containing triazolam shall comply with §§ 1306.01-1306.06 and §§ 1306.21-1306.25 of Title 21 of the Code of Federal Regulations.

7. **Importation and Exportation.** All importation and exportation of triazolam shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

8. **Criminal Liability.** The Acting Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to triazolam not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful.

Pursuant to 5 U.S.C. 605(b), the Acting Administrator certifies that the placement of triazolam into Schedule IV of the Controlled Substances Act will not have a significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). This action involves the initial control of a substance not previously approved for marketing in the United States.

In accordance with the provisions of 21 U.S.C. 811(a), this placement of triazolam into Schedule IV of the CSA is a formal rulemaking "on the record after opportunity for a 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 of Executive Order 12291 (46 FR 13193, Feb. 19, 1981).

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

PART 1308—[AMENDED]

Under the authority vested in the Attorney General by Section 201(a) of the CSA (21 U.S.C. 811(a)) and delegated to the Acting Administrator of the Drug Enforcement Administration by the Department of Justice regulations (28 CFR 0.100), the Acting Administrator hereby orders that § 1308.14(c) of Title 21 of the Code of Federal Regulations be amended by adding (c)(24) to read as follows:

§ 1308.14 Schedule IV.

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(c) * * *

(24) Triazolam 2887

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Dated: December 20, 1982.

Francis M. Mullen, Jr.,
Acting Administrator, Drug Enforcement
Administration.

(FR Doc. 82-34990 Filed 12-27-82; 8:45 am)

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[T.D. ATF-121; Ref: Notice No. 371]

California Shenandoah Valley Viticultural Area

AGENCY: Bureau of Alcohol, Tobacco and Firearms, Department of the Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: This final rule establishes a viticultural area in portions of Amador and El Dorado Counties in California to be known as "Shenandoah Valley" qualified by the word "California." The Bureau of Alcohol, Tobacco and Firearms (ATF) believes establishment of the California Shenandoah Valley as a viticultural area and its subsequent use as an appellation of origin on wine labels and in wine advertisements will

help consumers better identify the wines they may purchase.

EFFECTIVE DATE: January 27, 1983.

FOR FURTHER INFORMATION CONTACT:

James A. Hunt, Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue, NW., Washington, DC 20226 (202-566-7626).

SUPPLEMENTARY INFORMATION:

Background

On August 23, 1978, ATF published Treasury Decision ATF-53 (43 FR 37672, 54624) revising regulations in 27 CFR Part 4. These regulations allow the establishment of definite viticultural areas. The regulations also allow the name of an approved viticultural area to be used as an appellation of origin on wine labels and in wine advertisements.

Section 4.25a(e)(1), Title 27, CFR, defines an American viticultural area as a delimited grapegrowing region distinguishable by geographical features. Section 4.25a(e)(2), outlines the procedure for proposing an American viticultural area. Any interested person may petition ATF to establish a grape growing region as a viticultural area.

Petition

ATF received a petition from the Amador County Wine Grape Growers Association proposing an area in Amador County, California, as a viticultural area to be known as "Shenandoah Valley." The area consists of approximately 10,000 acres of which about 1,200 acres are vineyards. The petitioner asked for the Shenandoah Valley viticultural area to be situated to the north and west of Fiddletown, California, and to the north and east of Plymouth, California.

In response to the petition, ATF published a notice of proposed rulemaking, Notice No. 371, in the Federal Register on April 13, 1981, (46 FR 21623) with a 60 day comment period. This comment period was then extended for an additional 30 days. Several requests were received for public hearings by interested persons in California and Virginia. Hearings were held in California on December 7 and 8, 1981, and in Virginia on January 12 and 13, 1982.

Evidence Relating To the Name

Testimony at the hearings established that the area derived its name from settlers from Virginia drawn to the area during the gold rush. The petition states and witnesses testified, among other things, that: