Proposed Rules

Federal Register
Vol. 68, No. 212
Monday, November 3, 2003

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, and 1307

[Docket No. DEA–240P]

RIN 1117–AA75

Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: Because long term care facilities (LTCFs) generally do not have pharmacies on site and are not registered with DEA, they typically receive controlled substances prescribed for specific patients in 30 day supplies, although smaller supplies are sometimes used. As patients leave or their medication needs to be changed, the LTCFs accumulate stocks of excess controlled substances. The excess stocks can result in significant problems with waste and disposal and present opportunities for diversion of controlled substances. DEA is proposing changes to its existing regulations to allow, where State laws permit, for pharmacy installation of automated dispensing systems (ADSs) at LTCFs. Automated dispensing systems would allow dispensing of single dosage units and mitigate the problem of excess stocks and disposal.

DATES: Written comments must be postmarked on or before January 2, 2004.

ADDRESSES: Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

I. Background

Legal Authority

DEA enforces the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*), as amended. DEA regulations implementing this statute are published in Title 21 of the Code of Federal Regulations (CFR), Part 1300 to end. These regulations are designed to establish a framework for the legal distribution of controlled substances to deter their diversion to illegal purposes and to ensure that there is a sufficient supply of these drugs for legitimate medical purposes. Controlled substances are those substances listed in the schedules of the CSA and 21 CFR 1308.11–1308.15, and generally include narcotics, stimulants, depressants, hallucinogens, and anabolic steroids that have a high potential for abuse and dependency. DEA's regulations require that persons involved in the manufacture, distribution, research, dispensing, import, and export of controlled substances register with DEA, keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or otherwise disposed of.

Controlled Substances at Long Term Care Facilities (LTCFs)

Patients at LTCFs receive numerous medications, including controlled substances. Unlike hospitals, LTCFs are rarely DEA registrants. Patients at these facilities are usually seen by their personal physicians, who prescribe any necessary medication. These prescriptions are filled by retail pharmacies and delivered to the LTCFs for patients' use. Because LTCFs are not registrants and generally do not have physicians or pharmacists on staff, they may not order and maintain stocks of controlled substances to be dispensed under the order of a practitioner as occurs in hospitals. Instead, the LTCF holds the controlled substance medications that are dispensed by prescription to the specific patients by a provider pharmacy in a custodial manner for administration to the patient. Any controlled substance medications that are not ultimately administered to the individual specific patient are waste that must be disposed of. Although DEA permits pharmacies to dispense a prescription for a LTCF patient on a daily or dosage unit basis rather than dispense the entire quantity prescribed, reimbursement rules under Medicare and Medicaid and other third party payors make daily dispensing financially unattractive for pharmacies; pharmacies are allowed a limited number of dispensing fees plus the calculated cost of the medication per month. As a consequence, pharmacies routinely dispense the entire prescription to the patient at once.

A result of this dispensing practice is that when patients leave the facility or their medications change, the LTCF is left with excess controlled substances, which must be disposed of to avoid diversion. Because they are not registrants, the LTCFs may not transfer the substances to either the pharmacy that supplied them or to a reverse distributor for disposal. The LTCF must dispose of the excess controlled substances directly.

Previous DEA Actions

DEA has frequently been asked to assist in resolving this matter. The principal concern has been to prevent the accumulation of controlled substances that are dispensed but not administered to the patient. DEA has attempted to address this problem through the establishment of partial dispensing provisions for Schedules II–V prescriptions (including unit-dose dispensing, if desired), to limit the quantity of controlled substances dispensed at one time and avoid waste if the treatment was changed or discontinued. According to the pharmacy industry, however, dispensing fees, reimbursement practices, and difficulties in educating practitioners regarding the need to prescribe controlled substances in anticipation of a patient's actual need for the controlled substance have, for the most part, precluded using that approach.

Current DEA Regulations

Although most LTCFs are not registered with DEA, DEA regulations allow a LTCF to register, if licensed by its State to handle controlled substances. DEA issues a registration in one of the following categories based upon the type of license/permit issued

by a State and the authorized activities associated with the license/permit:

- Retail pharmacy—A pharmacy located on-site at the LTCF maintains stocks of controlled substances and a pharmacist dispenses patient-specific controlled substances to residents of the LTCF who have prescriptions for the substances.
- Hospital/clinic—The LTCF maintains institutional stocks of controlled substances for dispensing by a pharmacist for administration to residents under medication orders from a practitioner.
- Mid-Level Practitioner—Controlled substance activities are limited to those authorized by the individual State.
- Practitioner—An individual practitioner, such as the Medical Director of the LTCF, registers at the site of the LTCF and is responsible for the handling of controlled substances utilized at the LTCF.

Request for Information

On April 25, 2001, DEA published a notice in the **Federal Register** (66 FR 20833) soliciting comments and suggestions on the problem of excess controlled substances at LTCFs. Almost two dozen comments were received from a range of organizations and individuals, including State agencies, automated dispensing system (ADS) manufacturers, trade associations, and pharmaceutical providers. Information received in response to that notice is discussed below.

II. Discussion of the Proposed Rule

DEA's Proposal

To further address the issue of excess controlled substances in LTCFs, DEA is proposing to allow a provider pharmacy to register at the site of the LTCF and store controlled substances in an ADS. An ADS is conceptually similar to a vending machine. A pharmacy stores bulk drugs in the ADS in separate bins or containers and programs and controls the ADS remotely. Only authorized staff at the LTCF would have access to its contents, which are dispensed on a single-dose basis at the time of administration pursuant to a prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the drugs would not be considered dispensed until the system provided them, drugs in the ADS would be pharmacy stock, not waste.

Specifically, DEA is proposing the definition of ''automated dispensing system'' as follows: ''a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.''

The key elements of an automated dispensing system would be the following:

- State authorization for pharmacies to locate stock in the automated dispensing systems at the LTCF.
- Establishment through State regulation of the necessary and appropriate policies and protocols with respect to access to pharmacy stock by LTCF nursing personnel, ensuring secure storage of the controlled substances, transfer of the controlled substances from the primary pharmacy location to the LTCF site, and related issues.
- Issuance of a DEA registration to the provider pharmacy at the LTCF as a separate location, based on its current DEA registration and without additional application fees.

DEA is proposing to allow the use of automated dispensing systems as an option, not a requirement. DEA recognizes that there are reasons why ADSs may not work in many circumstances, but believes that some LTCFs will find ADSs a viable solution for preventing accumulation of excess controlled substances. This technology has a number of advantages, including the following:

- It can substantially reduce controlled substance waste, thereby providing significant cost savings to purchasers of controlled substances. It also can significantly reduce the time and other costs associated with maintaining patient medication stocks and disposal of excess stocks for LTCFs.
- With single-dose dispensing, secure storage, and controlled access, it can help to control drug inventory and increase accountability.
- With an increasing amount of controlled substances in use as the LTCF population grows, it can help control the opportunities for drug diversion.
- It recognizes advancements made in technology and provides the option of using the most current technology in a broader array of circumstances.
- With the current pharmacist shortage, it relieves dispensing pharmacists of a number of manual steps involved in drug handling.
- For consulting pharmacists in their responsibilities for drug regimen review, it provides enhanced tools with a full range of accurate data available online because the data are captured automatically.

III. Use of Automated Dispensing Systems

Existing State Laws and Regulations

To implement this solution, States would need to grant approval (*i.e.*, a license, permit, or other authorization) for the provider pharmacy to function at the location of the LTCF using an ADS, and establish policies and procedures regarding system security, access, and the like. States could define such an operation so as to avoid the many peripheral requirements of traditional pharmacies such as sinks, reference books, etc.

Other Options DEA Considered

As solicited by the April 25, 2001, request for information, one commenter suggested that LTCFs should be able to obtain a limited registration for purposes of contracting with reverse distributors for waste disposal. DEA believes that, while this option has merit on the issue of disposal, it does not address control of waste and it potentially imposes additional disposal costs on LTCFs. Further, LTCFs would need state authorization to handle controlled substances in the manner envisioned here before DEA could issue them a DEA registration. In addition, LTCFs would be required to comply with DEA recordkeeping and reporting requirements.

Another suggestion was to address directly the problem of excess medications being sent to facilities in the first place. Specifically, the commenter suggested that practitioners' routine medication orders not be sent to the LTCF unless actually necessitated by the patient. A related suggestion was to change reimbursement standards that are, at least in part, responsible for the current situation. Unfortunately, these are not issues that DEA is empowered to address.

Yet another suggestion was to authorize limited permit pharmacies at LTCFs 2–3 days per week. It is unclear to DEA how this option of a ''part-time'' pharmacy resolves the current problems.

Finally, there were various suggestions about a pharmacy maintaining controlled substances as floor stock at LTCFs as an alternative to an ADS. DEA notes that this option would still require someone to be registered at the LTCF (either the pharmacy or the LTCF itself). The significant concern with this option is the need to maintain accountability and security for the controlled substances, which DEA believes is much easier to do with an ADS.

DEA is not opposed to making other options available to LTCFs and pharmacies, as long as they address the problems discussed in this proposal, maintain strict levels of security and accountability, and comply with Federal and State regulatory requirements.

Other Comments on the April 25, 2001 Notice

A number of commenters, including current ADS users, supported the option of using ADSs for controlled substances at LTCFs, believing they can reduce waste and disposal problems, eliminate opportunities for medication errors, improve patient care, and/or reduce diversion of controlled substances.

A number of commenters also suggested this was not a good idea, citing primarily one or more of the following reasons:

- ADSs are expensive to finance and maintain.
- State laws and regulations will need to be changed.
- Registration at each location would be burdensome and expensive.
- The logistics associated with use and maintenance of the systems are complicated.
- There are substantial security concerns. Commenters provided examples of where security issues (*e.g.*, diversion, misdispensing) have arisen.
- ADSs do not represent a total solution to waste/disposal problems.

Several of these concerns are addressed elsewhere in this preamble. To the extent DEA does not specifically address some of these issues, DEA would reiterate that it recognizes this option will not work in all situations. However, DEA believes that ADS systems should be an *option* to be used where it does make sense and is otherwise permissible.

Medication Delivery Systems Currently Used by LTCFs

DEA is not suggesting that unit-dose delivery systems or other medication delivery systems that most LTCFs use be replaced. DEA recognizes that the cost of an automated dispensing system as well as other requirements associated with its use at a LTCF may not be warranted in many cases. Therefore, the use of an automated dispensing system for storage and dispensing of controlled substances to residents of LTCFs would be an option available to the provider pharmacy.

Specific Proposed Regulatory Changes

Current Federal law does not prohibit the use of ADSs for storage and dispensing of controlled substances at LTCFs where the LTCF itself is a DEA registrant. However, to successfully implement the approach being proposed here requires several regulatory revisions:

- Section 1300.01 would be modified to include a definition of automated dispensing system.
- Section 1301.17 would be modified to incorporate an additional ''special procedure'' for the type of registrations that are the subject of this notice. Specifically, retail pharmacies applying for a separate registration to operate an ADS at a LTCF will need to provide as part of their registration application an affidavit attesting to the existence of a State license, permit, or other authorization for activities at the LTCF.
- Section 1301.27 would be added to indicate that only retail pharmacies may operate automated dispensing systems at long term care facilities. The section would further indicate that a retail pharmacy must maintain a separate registration at each long term care facility location at which automated dispensing systems are installed and operated, and that if more than one retail pharmacy operates an automated dispensing system at a long term care facility, each retail pharmacy must maintain its own separate registration at that facility. Finally, this section indicates that retail pharmacies applying for separate registrations to install and operate automated dispensing systems at long term care facilities would be exempt from application fees for those separate registrations.
- Section 1304.04 would be revised to permit a registered retail pharmacy with one or more associated registrations at LTCFs to keep all records for those LTCF locations at the retail pharmacy site or other approved central location.
- Since the provider pharmacy would likely be ordering controlled substances for multiple LTCFs that it services, § 1307.11(b) which limits total distribution by a practitioner to 5 percent of all controlled substances dispensed in the course of a year would be amended to provide an exemption for this activity.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small business entities. This proposed rule provides the option of using an automated dispensing system to dispense controlled substances to patients at long term care facilities. Facilities which currently use automated dispensing systems for the dispensing of noncontrolled substances and, where permitted by DEA registration, for controlled substances report in industry literature that, while there are costs associated with the lease or purchase of an automated dispensing system, automated dispensing systems have the following benefits:

- Significantly reduce drug waste. Various studies over the past ten years have indicated that between 4 and 10 percent of medications at long term care facilities are wasted. Additional reports indicate that the use of an automated dispensing system reduces this waste by 90 percent.
- Significant cost savings for payors. As noted previously, automated dispensing systems have the potential to reduce the cost of medications dispensed because medications are dispensed in a ''just in time'' manner for administration rather than dispensing a larger quantity of medication less frequently, which can create waste.
- Reduce nursing and pharmacy labor costs. Nurses and pharmacy personnel no longer must prepare medications for dispensing to individual patients. Time is also saved by nursing staff due to the fact that medication administration records are now maintained electronically. Often, this time is then redirected to providing patient care.
- Reduce the potential for medication dispensing and administration errors. Automated dispensing systems provide greater accuracy in the dispensing and administration of medications.

Because the proposed rule does not require the use of automated dispensing systems, DEA believes that only pharmacies and LTCFs which find use of these systems cost-effective will adopt this approach.

Executive Order 12866

The Deputy Assistant Administrator, Office of Diversion Control, further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). It has been determined that this is not a significant regulatory action because it does not impose costs above $100 million a year or raise novel issues. Therefore, this action has not been reviewed by the Office of Management and Budget. Rather, this NPRM proposes to permit the installation of automated dispensing systems at long term care facilities by provider pharmacies, so long as state

regulations permit such installation. The use of automated dispensing systems by long term care facilities provides another alternative to address the problem of accumulation of surplus controlled substances at long term care facilities. DEA believes that persons choosing to utilize this method of dispensing controlled substances to patients at long term care facilities may realize cost savings. More importantly to DEA, the use of such systems should reduce the accumulation of excess controlled substances at these facilities, thereby reducing the potential for diversion of these controlled substances.

Paperwork Reduction Act

This rule proposes that a retail pharmacy currently registered with DEA would be required to apply for separate registration at the location of the long term care facility at which it intends to install and operate an automated dispensing system. Application for registration is made using currently existing DEA registration forms (DEA Form 224 for registration and 224A for registration renewal). DEA estimates that approximately 100 persons per year will apply for registration to operate automated dispensing systems at long term care facilities. Therefore, DEA is revising its OMB-approved information collection (OMB 1117–0014) to reflect this increased burden due to this program change.

Further, within this rulemaking DEA is proposing that at the time of application for this separate registration at the long term care facility by the retail pharmacy, the applicant must include with their application for registration (DEA Form 224) an affidavit as to the existence of State authorization to operate the automated dispensing system at the long term care facility. DEA has provided a format for the affidavit as part of its proposed regulations. This affidavit is exempt from the requirements of the Paperwork Reduction Act (5 CFR 1320.3(h)(1)).

Executive Order 12988

This proposed rule meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rule does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $113,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects

21 CFR Part 1300

Definitions, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1304

Drug traffic control, Prescription drugs.

21 CFR Part 1307

Drug traffic control.

For the reasons set out above, 21 CFR parts 1300, 1301, 1304, and 1307 are proposed to be amended as follows:

PART 1300—DEFINITIONS [AMENDED]

1. The authority citation for Part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

2. Section 1300.01 is proposed to be amended by adding a new paragraph (b)(45) to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

(45) The term automated dispensing system means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES [AMENDED]

3. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 956.

4. § 1301.17 is proposed to be revised by redesignating paragraph (c) as paragraph (d) and adding new paragraph (c) to read as follows:

§ 1301.17 Special procedures for certain applications.

* * * * *

(c) If at the time of application for a separate registration at a long term care facility, the retail pharmacy has been issued a license, permit, or other form of authorization from the appropriate State agency to install and operate an automated dispensing system for the dispensing of controlled substances at the long term care facility, the applicant must include with his/her application for registration (DEA Form 224) an affidavit as to the existence of the State authorization. Exact language for this affidavit may be found at the DEA Diversion Control Program web site. The affidavit must include the following information:

(1) The name and title of the corporate officer or official signing the affidavit;

(2) The name of the corporation, partnership or sole proprietorship operating the retail pharmacy;

(3) The name and complete address (including city, state, and Zip code) of the retail pharmacy;

(4) The name and complete address (including city, state, and Zip code) of the long term care facility for which DEA registration is sought;

(5) Certification that the named retail pharmacy has been authorized by the state Board of Pharmacy or licensing agency to install and operate an automated dispensing system for the dispensing of controlled substances at the named long term care facility (including the license or permit number, if applicable);

(6) The date on which the authorization was issued;

(7) Statements attesting to the following:

(i) The affidavit is submitted to obtain a Drug Enforcement Administration registration number;

(ii) If any information is false, the Administration may immediately suspend the registration for this activity

and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety;

(iii) Any false information contained in this affidavit may subject the person signing this affidavit and the above-named corporation/partnership/business to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than $30,000 or both;

(8) Signature of the person authorized to sign the Application for Registration for the named retail pharmacy;

(9) Notarization of the affidavit.

* * * * *

5. § 1301.27 is proposed to be added to read as follows:

§ 1301.27 Separate registration by retail pharmacies for installation and operation of automated dispensing systems at long term care facilities.

(a) A retail pharmacy may install and operate automated dispensing systems, as defined in § 1300.01 of this chapter, at long term care facilities, pursuant to the requirements of § 1301.17 of this part. No person other than a retail pharmacy may install and operate an automated dispensing system at a long term care facility.

(b) Retail pharmacies installing and operating automated dispensing systems at long term care facilities must maintain a separate registration at the location of each long term care facility at which automated dispensing systems are located. If more than one retail pharmacy operates automated dispensing systems at the same long term care facility, each retail pharmacy must maintain a registration at the long term care facility.

(c) A registered retail pharmacy applying for a separate registration to operate an automated dispensing system for the dispensing of controlled substances at a long term care facility is exempt from application fees for any such additional registrations.

PART 1304—RECORDS AND REPORTS OF REGISTRANTS [AMENDED]

6. The authority citation for part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 871(b), 958(e), 965.

7. § 1304.04 is proposed to be amended by revising paragraph (a) to read as follows:

§ 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other record required to be kept under this part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to § 1305.13 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge. All notifications must include the following:

(i) The nature of the records to be kept centrally.

(ii) The exact location where the records will be kept.

(iii) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(iv) Whether central records will be maintained in a manual or computer readable form.

(2) A registered retail pharmacy that possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this part for those additional registered sites at the retail pharmacy or other approved central location.

* * * * *

PART 1307—MISCELLANEOUS [AMENDED]

8. The authority citation for Part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b).

9. § 1307.11 is proposed to be amended by adding a new paragraph (c) to read as follows:

§ 1307.11 Distribution by dispenser to another practitioner or reverse distributor.

* * * * *

(c) The distributions that a registered retail pharmacy makes to automated dispensing systems at long term care facilities for which the pharmacy also holds registrations do not count toward the 5 percent limit in paragraphs (a)(4) and (b) of this section.

Dated: October 24, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 03–27511 Filed 10–31–03; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Notice No. 21]

RIN 1513–AA58

Proposed Ribbon Ridge Viticultural Area (2002R–215P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau has received a petition proposing the establishment of the ''Ribbon Ridge'' viticultural area in northern Yamhill County, Oregon, between Newberg and Gaston. This proposed viticultural area, which measures approximately 1.75 miles in width and 3.5 miles in length, lies approximately 22 miles southwest of Portland, Oregon, and 40 miles inland from the Pacific Ocean. As of 2002, at least 14 vineyards, totaling over 286 acres currently planted, plus 3 commercial wineries exist within the proposed boundaries of the Ribbon Ridge viticultural area. We believe the use of viticultural area names as appellations of origin in wine labeling and advertising helps consumers identify wines. It also allows wineries to better designate the specific grape-growing area in which their wine grapes were grown. We invite comments on this proposal.

DATES: We must receive written comments on or before January 2, 2004.

ADDRESSES: You may send comments to any of the following addresses—

- Chief, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 50221, Washington, DC 20091–0221 (Attn: Notice No. 21);
- 202–927–8525 (facsimile);
- *nprm@ttb.gov* (e-mail); or
- *http://www.ttb.gov* (An online comment form is posted with this notice on our Web site).

You may view copies of the proposed regulations and any comments received on this notice online at *http://www.ttb.gov/alcohol/rules/index.htm* and by appointment at our reference