



JUL 8 2005

Center for Mental Health Services
Center for Substance Abuse
Prevention
Center for Substance Abuse
Treatment
Rockville MD 20857

Dear Colleague:

This letter is to notify you of new Drug Enforcement Administration (DEA) regulations that implement the Drug Addiction Treatment Act of 2000 (DATA 2000). The new rules affect physicians who are certified to prescribe Subutex and Suboxone for addiction treatment ("certified physicians"), and those contemplating certification. The intent of the June 23, 2005, Final Rule is to accomplish the goals of DATA 2000 (expanding access to treatment by permitting office-based opioid treatment), while preventing the diversion of Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically approved for maintenance and detoxification treatment.

Beginning July 25, 2005, under Title 21 of the Code of Federal Regulations Parts 1301 and 1306, a number of requirements will go into effect.:

1. Section 1306.05 (a) will require certified practitioners to include their unique identification number on the prescriptions they issue for Subutex and Suboxone for addiction treatment.
2. Certified physicians will also be required to keep records of all prescriptions written for controlled substances listed in any schedule for maintenance or detoxification treatment of an individual (§1304.03 (c)). Records required to be maintained include inventories, records of receipt, reports of theft or loss, destruction of controlled drugs, and records of dispensing. These records must be maintained for two years. The Center for Substance Abuse Treatment will be working with DEA to develop additional guidance to assist physicians with these new requirements. At this time, certified physicians are advised to keep separate records for their Subutex and Suboxone addiction treatment patients.
3. Finally, the preamble to the Final Rule reminds certified physicians that dispense Schedule III, IV, or V, controlled substances, including Subutex and Suboxone, that they are subject to the storage and security requirements under 21 CFR § 1301.75(b). Schedule III, IV, and V controlled drugs must be stored in a securely locked, substantially constructed cabinet.

It is important to also note that while opioid treatment programs are not limited in the number of patients to whom they may administer and dispense Schedule III, IV, and V controlled substances for detoxification and maintenance, the 30- patient limit remains in effect for individual practitioners as well as group practices.

If you have any questions regarding these new requirements, please contact Mr. Nicholas Reuter at 240-276-2716 or Nicholas.Reuter@samhsa.hhs.gov for additional information.

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM
Director
Center for Substance Abuse Treatment

Enclosure

cattle of breeding age. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

§ 522.1451 [Amended]

■ 3. Section 522.1451 is amended by revising the section heading to read "Moxidectin for suspension."

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

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

Authority: 21 U.S.C. 342, 360b, 371.

■ 5. Section 556.426 is amended by redesignating paragraphs (b)(1)(i) through (b)(1)(iii) as paragraphs (b)(1)(ii) through (b)(1)(iv); by revising newly redesignated paragraphs (b)(1)(ii) and (b)(1)(iv); and by adding new paragraphs (b)(1)(i) and (c) to read as follows:

§ 556.426 Moxidectin.

* * * * *

(b) * * *

(1) * * *

(i) *Fat (the target tissue)*. The tolerance for parent moxidectin (the marker residue) is 900 parts per billion (ppb).

(ii) *Liver*. The tolerance for parent moxidectin (the marker residue) is 200 ppb.

(iii) * * *

(iv) *Milk*. The tolerance for parent moxidectin (the marker residue) is 40 ppb.

* * * * *

(c) *Related conditions of use*. See § 522.1451 of this chapter.

Dated: June 10, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05-12421 Filed 6-22-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Mometasone Furoate, Clotrimazole Otic Suspension; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 Schering-Plough Animal Health Corp. The supplemental NADA provides for a new container size, a 7.5-gram dropper bottle, from which gentamicin sulfate, mometasone furoate, clotrimazole otic suspension may be administered for the treatment of otitis externa in dogs. The regulations are also being amended to correct the description of a previously approved container size. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective June 23, 2005.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: melanie.berson@fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 141-177 for use of MOMETAMAX (gentamicin sulfate, U.S.P.; mometasone furoate monohydrate; and clotrimazole, U.S.P.) Otic Suspension for the treatment of otitis externa in dogs. The supplement provides for a new container size, a 7.5-gram dropper bottle. The supplemental NADA is approved as of June 1, 2005, and the regulations are amended in 21 CFR 524.1044h to reflect the approval.

The regulations are also being amended to correct the description of a previously approved container size. This action is being taken to improve the accuracy of the regulations.

The agency has determined under 21 CFR 25.33(a)(4) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subject in 21 CFR Part 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 2. Section 524.1044h is amended by revising paragraphs (b) and (c)(1) to read as follows:

§ 524.1044h Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension.

* * * * *

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. For dogs weighing less than 30 pounds (lb), instill 4 drops from the 7.5-, 15-, or 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or more, instill 8 drops from the 7.5-, 15-, or 30-g bottle into the ear canal (4 drops from the 215-g bottle), once or twice daily for 7 days.

* * * * *

Dated: June 15, 2005.

Steven D. Vaughn,

Director, Office of New Animal Drug

Evaluation, Center for Veterinary Medicine.

[FR Doc. 05-12402 Filed 6-22-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1306

[Docket No. DEA-202F]

RIN 1117-AA68

Authority for Practitioners To Dispense or Prescribe Approved Narcotic Controlled Substances for Maintenance or Detoxification Treatment

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is amending its regulations to allow qualified practitioners not otherwise registered as a narcotic treatment program to dispense and prescribe to narcotic dependent persons Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment. This Final Rule is in response to amendments to the Controlled Substances Act by the Drug Addiction Treatment Act of 2000 (DATA) that are designed to expand and

improve treatment of narcotic addiction. This Final Rule is intended to accomplish the goals of DATA while preventing the diversion of Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for maintenance/detoxification treatment.

DATES: *Effective Date:* July 25, 2005.

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:

Technical Modification Regarding This Final Rule

In its Notice of Proposed Rulemaking (NPRM) proposing amendment of the regulations to implement the Drug Addiction Treatment Act of 2000, DEA proposed a new § 1301.27 of Title 21 of the Code of Federal regulations. Subsequent to publication of that NPRM, DEA published a Final Rule entitled "Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities" (70 FR 25462, May 13, 2005; Docket No. DEA-240, RIN 1117-AA75) which amended Title 21 by adding a new § 1301.27. Therefore, amendments regarding the Drug Addiction Treatment Act of 2000 which were proposed to be included in new § 1301.27 are being finalized at § 1301.28.

Background

On October 17, 2000, Congress passed the Drug Addiction Treatment Act of 2000 (DATA), amending the Controlled Substances Act (CSA) to establish "waiver authority for physicians who dispense or prescribe certain narcotic drugs for maintenance treatment or detoxification treatment" (Pub. L. 106-310, title XXXV; 114 Stat. 1222). Prior to DATA, the Controlled Substances Act and DEA regulations required practitioners who wanted to conduct maintenance or detoxification treatment using narcotic controlled drugs to be registered as a Narcotic Treatment Program (NTP) in addition to the practitioner's personal registration. The separate NTP registration authorized the practitioner to dispense or administer, but not prescribe, narcotic drugs.

With passage of DATA, DEA published a notice of proposed rulemaking (68 FR 37429, June 24, 2003) to amend the regulations affecting maintenance and detoxification treatment for narcotic treatment by establishing an exemption from the separate registration requirement.

This Final Rule will permit the following:

(1) Qualifying physicians to dispense and prescribe Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment.

(2) Narcotic dependent patients to have one-on-one consultations with a practitioner in a private practice setting.

(3) Pharmacies to fill prescriptions for Schedule III, IV, and V narcotic controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment.

(4) Practitioners to offer maintenance and detoxification treatment to a limited number of patients in their private practices without having a second registration as a NTP.

The exemption and other amendments established by this Final Rule apply to individual practitioners working in traditional NTPs as well as any other practice setting. This rule does not affect the existing prohibition against prescribing any Schedule II narcotic controlled drugs for maintenance or detoxification treatment.

Conditions for Qualifying for an Exemption Under Section 1301.28

A practitioner who wishes to qualify for the exemption in new § 1301.28 must submit a notification of intent to dispense or prescribe narcotic controlled drugs to opiate-dependent patients to the U.S. Department of Health and Human Services (DHHS). In the notification the practitioner must certify that all of the following are true:

(1) The practitioner is a "qualifying physician." A practitioner is a "qualifying physician" if he or she is licensed under State law and has specific medical certification, training, or experience in maintenance or detoxification treatment. The Secretary of DHHS has established criteria to be used for determining whether a practitioner is a "qualifying physician."

(2) The practitioner has the capacity to refer the patients, to whom the practitioner will provide specifically approved narcotic drugs or combinations of narcotic drugs, for appropriate counseling and other appropriate ancillary services.

(3) The total number of patients treated for opiate dependence by the practitioner who is not a member of a group practice will not exceed 30 at any one time, unless modified by regulation by the Secretary of DHHS.

(4) If the practitioner is a member of a group practice, the total number of

patients treated for opiate dependence by the group practice of which the practitioner is a member will not exceed 30 at any one time, unless modified by regulation by the Secretary of DHHS.

The Schedule III, IV or V narcotic drugs or combination of narcotic drugs dispensed or prescribed by the practitioner must meet the following two conditions:

(1) The drugs are approved by FDA specifically for use in maintenance treatment or detoxification treatment.

(2) The drugs have not been the subject of an adverse determination by DHHS that their use requires additional standards respecting the qualifications of practitioners or the quantities of the drugs that may be provided for unsupervised use.

Agency Response To Notification and the Issuance of an Identification Number

When DHHS receives a notification of intent to dispense or prescribe narcotic controlled drugs for maintenance or detoxification treatment it will forward a copy of the notification to DEA. From the date DHHS receives the notification it will have up to 45 days to review the practitioner's qualifications and make a determination as to whether the practitioner meets all of the requirements for the exemption. While DHHS is conducting its determination, DEA will conduct its own review to determine if the practitioner has the appropriate DEA registration in accordance with 21 U.S.C. 823(f).

Once DHHS has made its determination, it will send the findings to DEA. If DEA determines that the practitioner has the appropriate DEA registration in accordance with 21 U.S.C. 823(f), then DEA will issue the practitioner an identification number as soon as either of the following conditions occurs: (1) DEA receives the positive determination from DHHS before the conclusion of the 45-day review period, or (2) the 45-day review period has concluded and no DHHS determination has been received.

If HHS denies certification to a practitioner or withdraws a certification once it is issued, then DEA will not issue the practitioner an identification number or will withdraw the identification number if one has been issued. Under § 1301.28(d) the practitioner is required to include the identification number on all records when dispensing and on all prescriptions when prescribing Schedule III, IV, or V narcotic controlled drugs for use in maintenance or detoxification treatment.

Exception to the 45-Day Review Period

The practitioner does not have to wait for receipt of an identification number from DEA if the practitioner is in compliance with § 1301.28(e). The practitioner can begin dispensing or prescribing during the 45-day review period if all of the following requirements are met:

(1) The practitioner has submitted, in good faith, a written notification under § 1301.28(b).

(2) The practitioner reasonably believes that the conditions specified in § 1301.28(b) and (c), regarding the practitioner and the narcotic drugs, have been met.

(3) The practitioner reasonably believes that prescribing or dispensing the narcotic drugs would facilitate the treatment of an individual patient.

(4) The practitioner has notified both DHHS and DEA of the intent to do so.

(5) DHHS has not notified the registrant that he or she is not a qualifying physician.

(6) The practitioner has the appropriate DEA registration under 21 CFR 1301.13.

The practitioner may satisfy the fourth requirement by including within the notification required by § 1301.28(b) a statement of his or her intent to immediately commence prescribing or dispensing. If DHHS refuses to certify a practitioner or withdraws a certification once it is issued, then DEA will not issue the practitioner an identification number or will withdraw the identification number if one has been issued.

Violation of Section 1301.28(b)

If a practitioner dispenses or prescribes Schedule III, IV, or V narcotic drugs in violation of any of the conditions specified in § 1301.28(b), then DEA may revoke the practitioner's DEA registration in accordance with § 1301.36.

Due to the potential for diversion, and in an effort to verify compliance with these regulations, DEA intends to conduct at least two regulatory investigations per field office per year of practitioners dispensing and prescribing to narcotic dependent persons Schedule III, IV, and V narcotic controlled drugs approved by the FDA specifically for use in maintenance or detoxification treatment.

Practitioners in Traditional NTPs Treated the Same as Practitioners in Other Practice Settings

This Final Rule affects practitioners working in traditional NTPs the same as any other practitioners. Prior to this

final rule, practitioners, whether in a traditional NTP or any other setting, were not permitted to prescribe Schedule III, IV, and V narcotic controlled drugs for use in maintenance or detoxification treatment. This Final Rule applies to any "qualifying physician," working in a NTP or other setting, who wants to dispense or prescribe Schedule III, IV, and V narcotic controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment. However, as discussed further below, since narcotic treatment programs are not permitted to prescribe controlled substances, if a physician working at a narcotic treatment program wishes to prescribe Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment, then the physician must register separately as an individual practitioner with DEA and obtain a waiver pursuant to 21 CFR 1301.28 to conduct such treatment. The practitioner would not issue such prescriptions under the narcotic treatment program's DEA registration.

Additional Requirements

Section 1306.05(a) requires the practitioner to include on the prescription the identification number (issued under § 1301.28(d)) or written notice that the practitioner is acting under the good faith exception of § 1301.28(e). These prescriptions will be subject to all of the existing requirements of part 1306 that apply to prescriptions for controlled substances. To be valid, a prescription must be written for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice (§ 1306.04(a)). The prescription must be dated as of, and signed on, the day issued, must contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner (§ 1306.05(a)).

Under existing law practitioners are not normally required to keep records of prescriptions issued. However, DEA regulations (§ 1304.03(c)) do require records to be kept by practitioners prescribing controlled substances listed in any schedule for maintenance or detoxification treatment of an individual.

For conformity § 1306.04, Purpose of issue of prescription, and § 1306.07, Administering or dispensing of narcotic drugs, have been amended by this Final Rule. This Final Rule amends § 1306.04(c) to permit prescriptions for

Schedule III, IV, and V narcotic controlled drugs approved by FDA specifically for maintenance or detoxification treatment by practitioners who are in compliance with § 1301.28.

Section 1306.07(a) permits the administering and dispensing (but not prescribing) of narcotic drugs for detoxification or maintenance treatment only by practitioners who are separately registered as a Narcotic Treatment Program. This Final Rule adds paragraph (d) to § 1306.07 to permit a practitioner to administer or dispense (including prescribe) any Schedule III, IV, or V narcotic controlled drug approved by FDA specifically for use in maintenance or detoxification treatment if the practitioner is in compliance with § 1301.28. This Final Rule also revises § 1306.07(a) to improve the clarity of the language, as discussed in the Public Comments on the NPRM section below.

Refills

DEA regulations allow practitioners to authorize refills for Schedule III, IV, or V controlled substance prescriptions. Prescriptions for Schedule III, IV, and V controlled substances are subject to the requirements in §§ 1306.22 and 1306.23, regarding the refilling and partial filling of prescriptions. In addition, practitioners prescribing Schedule III, IV, or V narcotic drugs for use in maintenance or detoxification treatment are subject to all relevant State and Federal requirements that apply to prescriptions for controlled drugs.

Other Relevant Requirements Not Affected by the Final Rule

Practitioners who administer or dispense (other than by prescription) Schedule III, IV, or V narcotic drugs approved by FDA specifically for maintenance or detoxification treatment must maintain records and provide security for the controlled drugs in their possession. Records required to be maintained include inventories, records of receipt, reports of theft or loss, destruction of controlled drugs, and records of dispensing. These records must be maintained for two years.

The regulations also require practitioners to safeguard controlled drugs (§ 1301.75(b)). The Schedule III, IV, or V narcotic controlled drugs approved by FDA specifically for maintenance or detoxification treatment must be stored in a securely locked, substantially constructed cabinet.

Regulations on prescribing allow the use of a written prescription signed by a practitioner, or a facsimile of a written prescription signed by a practitioner, transmitted by the practitioner, or the practitioner's agent, to the pharmacy

(§ 1306.21). In addition, a practitioner may telephone the pharmacy with an oral prescription. The pharmacist must immediately reduce the oral prescription to writing, including all information required in § 1306.05, except for the signature of the practitioner (§ 1306.21(a)).

Public Comments on the NPRM

DEA received six comments in response to the proposed rule. Commenters included community health centers, hospitals, an industry association, and the Center for Substance Abuse Treatment of the Department of Health and Human Services (CSAT). While the commenters supported the general intent of the rule, they also requested changes to certain aspects of the rule. The following discussion summarizes the issues raised by commenters and DEA's response to these issues.

Practitioners Other Than Physicians

Three commenters requested that the rule be modified to permit mid-level practitioners, including physician assistants, nurse practitioners and, where states permit, pharmacists, who meet the appropriate training and certification criteria to be deemed "qualifying physicians" and, thus, to be able to prescribe Schedule III, IV and V narcotic controlled drugs for maintenance or detoxification treatment.

DEA Response: The final rule has not been modified to allow mid-level practitioners, such as pharmacists, nurse practitioners, and physician assistants to prescribe Schedule III, IV, and V substances for substance abuse treatment. In DATA Congress specified that physicians may prescribe these substances. This final rule is also consistent with the rules and policies of CSAT.

30 Patient Limit

One commenter expressed concern regarding the 30 patient limit, stating that it was difficult to treat all patients served by the facility without experiencing problems with this limit.

DEA Response: The 30 patient limit is specifically referenced in the law (21 U.S.C. 823(g)(2)(iii) and (iv)) where it is referred to as the "applicable number". The law specifically grants the Secretary of Health and Human Services the authority to change, by regulation, the applicable number. DEA does not have authority regarding the 30 patient limit, and, thus, is leaving the regulations unchanged.

Pharmacist Responsibilities

One commenter was concerned that pharmacists have the necessary information to ensure that a physician has made the good faith effort to obtain an identification number. The commenter also questioned whether the pharmacist is responsible for ensuring that only one patient is treated by the physician prior to receipt of the identification number. The commenter requested that DEA clarify in the final rule that pharmacists are not responsible for ensuring the "one patient" rule other than patients that the pharmacy serves.

Further, the same commenter questioned how the pharmacist will know if a physician goes over the 30 patient limit, and requested DEA clarify whether pharmacists would be responsible for enforcing this limit.

DEA Response: Pharmacists only need to be sure that the practitioner either has received an identification number or is claiming the good faith exception. Pharmacists are not responsible for ensuring that only one patient is treated by the practitioner prior to receipt of the identification number. The language in § 1301.28(e)(3) has been revised in the Final Rule to make this clear.

Pharmacists are also not covered by the 30-patient rule. Pharmacists are not required to investigate the validity of the practitioners' good faith claim nor their compliance with the 30-patient rule.

DEA wishes to note, however, that if a pharmacy becomes aware of circumstances in which it has reason to believe that a qualifying physician is violating either the good faith exception or the limit regarding the applicable number of patients which a qualifying physician is permitted to treat, DEA would expect the pharmacy to report this information to DEA as a matter of public interest.

The individual practitioner (physician) is responsible for compliance with the requirements of § 1301.28. The practitioner must submit to DHHS a separate notification letter for each patient the practitioner plans to treat under § 1301.28(e).

Physicians With Waivers

CSAT stated that it has received several inquiries from physicians with "waivers" who intend to treat patients in NTPs as well as other settings, including "drug-free" treatment programs. CSAT requested that the final rule should clarify that physicians with waivers do not need to register as NTPs to dispense buprenorphine products under the conditions set forth in DATA.

DEA Response: Individual practitioners with waivers do not need to register as NTPs to dispense buprenorphine products under the conditions set forth in DATA. These practitioners may treat patients in NTPs or other settings just as any other practitioner would in accordance with this Final Rule. Practitioners also must comply with all state requirements related to buprenorphine products, which may be more than DEA requirements.

DEA wishes to reiterate that narcotic treatment programs may administer or dispense directly, but not prescribe, narcotic drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to narcotic dependent persons for maintenance or detoxification treatment. Thus, narcotic treatment programs may administer or dispense directly Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment. Narcotic treatment programs are not limited in the number of patients to whom they may administer or dispense directly these controlled substances. Such controlled substances, however, may not be prescribed. If a physician working at a narcotic treatment program wishes to prescribe Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment, then the physician must register separately as an individual practitioner with DEA and obtain a waiver pursuant to 21 CFR 1301.28 to conduct such treatment. The practitioner would not issue such prescriptions under the narcotic treatment program's DEA registration.

Records

CSAT stated that since the CSA defines practitioners to include pharmacies, it was unclear from the NPRM (68 FR 37432) whether pharmacies are required to maintain records of dispensation.

DEA Response: In the preamble to the NPRM the use of the word practitioners was referring to the individual practitioners (physicians) who administer or dispense Schedule III, IV, or V narcotic drugs approved by the FDA specifically for maintenance or detoxification treatment. In addition, pharmacies are required to maintain records of all controlled substance dispensing.

Written Notification

CSAT requested that the Final Rule should clarify when a written notification is necessary. CSAT recommended allowing all forms of notification submission for "good faith" waivers.

DEA Response: The Final Rule has been modified to clarify the circumstances in which notification must be provided in writing. The requirement for written notification is contained in the law and DEA, therefore, has no authority to permit other forms of notification.

Issuance of an Order

CSAT questioned the requirement in § 1301.28(e)(5), that states that DEA will issue a practitioner an identification number if "the Secretary has not issued an order indicating that the registrant is not qualified under paragraph (d) of this section." CSAT stated that the limited review period does not permit sufficient time to issue "an order" to each physician with incomplete or deficient notifications. CSAT believed it should be sufficient to inform physicians of deficiencies by phone, fax, or letter. CSAT recommended that the language be revised to reflect "the Secretary has not notified the registrant that they are not qualified under paragraph (d) of this section."

DEA Response: The Final Rule has been modified to remove the language specifying that the Secretary must issue an order indicating that the registrant is not qualified. The revised language states that the Secretary has not notified the registrant that he or she is not qualified.

Administering or Dispensing of Narcotic Drugs

CSAT indicated that the language in § 1306.07(a) should clarify that qualifying physicians would only be able to administer or dispense directly those schedule III, IV, or V narcotic drugs that meet the legislated criteria under DATA. This would not include narcotic drugs listed in schedule II.

DEA Response: DEA agrees with this comment and has clarified the language of § 1306.07(a)(2) to remove the reference to § 1301.28 so that paragraph (a)(2) now states that the practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, has

reviewed this regulation and hereby certifies that it has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) and that it will not have a significant economic impact on a substantial number of small entities. This rule permits practitioners to prescribe Schedule III, IV, and V narcotic controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment without being separately registered with DEA as a NTP. Although virtually all entities affected would be small, the cost of determining eligibility and applying for a waiver is negligible. Further, the ability to prescribe Schedule III, IV and V narcotic controlled substances specifically approved by FDA for maintenance/detoxification treatment to narcotic dependent persons is not required; physicians choosing to conduct this treatment do so voluntarily and choose to apply for the waiver.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rule has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant rulemaking action. Therefore, this action has not been reviewed by the Office of Management and Budget. As noted above, this rule permits practitioners to prescribe Schedule III, IV, and V narcotic controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment without being separately registered with DEA as a NTP.

Executive Order 12988

This 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 \$115,000,000 or more 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 of 1996

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 1301

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

21 CFR Part 1306

Drug traffic control, Prescription drugs.

■ For the reasons set out above, 21 CFR Parts 1301 and 1306 are amended as follows:

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

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

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 951, 952, 953, 956, 957.

■ 2. Part 1301 is amended by adding § 1301.28 to read as follows:

§ 1301.28 Exemption from separate registration for practitioners dispensing or prescribing Schedule III, IV, or V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

(a) An individual practitioner may dispense or prescribe Schedule III, IV, or V narcotic controlled drugs or combinations of narcotic controlled drugs which have been approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment without obtaining the separate registration required by § 1301.13(e) if all of the following conditions are met:

(1) The individual practitioner meets the conditions specified in paragraph (b) of this section.

(2) The narcotic drugs or combination of narcotic drugs meet the conditions specified in paragraph (c) of this section.

(3) The individual practitioner is in compliance with either paragraph (d) or paragraph (e) of this section.

(b)(1) The individual practitioner must submit notification to the Secretary of Health and Human Services stating the individual practitioner's intent to dispense or prescribe narcotic drugs under paragraph (a) of this section. The notice must contain all of the following certifications:

(i) The individual practitioner is registered under § 1301.13 as an individual practitioner and is a "qualifying physician" as defined in section 303(g)(2)(G) of the Act (21 U.S.C. 823(g)(2)(G)).

(ii) The individual practitioner has the capacity to refer the patients to whom the individual practitioner will provide narcotic drugs or combinations of narcotic drugs for appropriate counseling and other appropriate ancillary services.

(iii) Where the individual practitioner is not a member of a group practice, the total number of such patients of the individual practitioner will not exceed 30 at any one time, unless regulations promulgated by the Secretary of Health and Human Services are modified.

(iv) Where the individual practitioner is a member of a group practice, the total number of such patients of the group practice will not exceed 30 at any one time, unless regulations promulgated by the Secretary of Health and Human Services are modified.

(2) If an individual practitioner wishes to prescribe or dispense narcotic drugs pursuant to paragraph (e) of this section, the individual practitioner must provide the Secretary of Health and Human Services the following:

(i) Notification as required under paragraph (b)(1) of this section in writing, stating the individual practitioner's name and DEA registration number issued under § 1301.13.

(ii) If the individual practitioner is a member of a group practice, the names of the other individual practitioners in the group and the DEA registration numbers issued to the other individual practitioners under § 1301.13.

(c) The narcotic drugs or combination of narcotic drugs to be dispensed or prescribed under this section must meet all of the following conditions:

(1) The drugs or combination of drugs have been approved for use in "maintenance treatment" or "detoxification treatment" under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

(2) The drugs or combination of drugs have not been the subject of an adverse

determination by the Secretary of Health and Human Services, after consultation with the Attorney General, that the use of the drugs or combination of drugs requires additional standards respecting the qualifications of practitioners or the quantities of the drugs that may be provided for unsupervised use.

(d)(1) After receiving the notification submitted under paragraph (b) of this section, the Secretary of Health and Human Services will forward a copy of the notification to the Administrator. The Secretary of Health and Human Services will have 45 days from the date of receipt of the notification to make a determination of whether the individual practitioner involved meets all requirements for a waiver under section 303(g)(2)(B) of the Act (21 U.S.C. 823(g)(2)(B)). Health and Human Services will notify DEA of its determination regarding the individual practitioner. If the individual practitioner has the appropriate registration under § 1301.13, then the Administrator will issue the practitioner an identification number as soon as one of the following conditions occurs:

(i) The Administrator receives a positive determination from the Secretary of Health and Human Services before the conclusion of the 45-day review period, or

(ii) The 45-day review period has concluded and no determination by the Secretary of Health and Human Services has been made.

(2) If the Secretary denies certification to an individual practitioner or withdraws such certification once it is issued, then DEA will not issue the individual practitioner an identification number, or will withdraw the identification number if one has been issued.

(3) The individual practitioner must include the identification number on all records when dispensing and on all prescriptions when prescribing narcotic drugs under this section.

(e) An individual practitioner may begin to prescribe or dispense narcotic drugs to a specific individual patient under this section before receiving an identification number from the Administrator if the following conditions are met:

(1) The individual practitioner has submitted a written notification under paragraph (b) of this section in good faith to the Secretary of Health and Human Services.

(2) The individual practitioner reasonably believes that the conditions specified in paragraphs (b) and (c) of this section have been met.

(3) The individual practitioner reasonably believes that the treatment of

an individual patient would be facilitated if narcotic drugs are prescribed or dispensed under this section before the sooner of:

(i) Receipt of an identification number from the Administrator, or

(ii) Expiration of the 45-day period.

(4) The individual practitioner has notified both the Secretary of Health and Human Services and the Administrator of his or her intent to begin prescribing or dispensing the narcotic drugs before expiration of the 45-day period.

(5) The Secretary has not notified the registrant that he/she is not qualified under paragraph (d) of this section.

(6) The individual practitioner has the appropriate registration under § 1301.13.

(f) If an individual practitioner dispenses or prescribes Schedule III, IV, or V narcotic drugs approved by the Food and Drug Administration specifically for maintenance or detoxification treatment in violation of any of the conditions specified in paragraphs (b), (c) or (e) of this section, the Administrator may revoke the individual practitioner's registration in accordance with § 1301.36.

PART 1306—PRESCRIPTIONS

■ 3. The authority citation for Part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

■ 4. Section 1306.04 is amended by revising paragraph (c) to read as follows:

§ 1306.04 Purpose of issue of prescription.

* * * * *

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.

■ 5. Section 1306.05 is amended by revising paragraph (a) to read as follows:

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. In addition, a prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for

“detoxification treatment” or “maintenance treatment” must include the identification number issued by the Administrator under § 1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of § 1301.28(e). Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

* * * * *

■ 6. Section 1306.07 is amended by revising the section heading and paragraph (a) and adding paragraph (d) to read as follows:

§ 1306.07 Administering or dispensing of narcotic drugs.

(a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependant person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

(1) The practitioner is separately registered with DEA as a narcotic treatment program.

(2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.

* * * * *

(d) A practitioner may administer or dispense (including prescribe) any Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of § 1301.28 of this chapter.

Dated: June 16, 2005.
William J. Walker,
Deputy Assistant Administrator, Office of Diversion Control.
 [FR Doc. 05-12440 Filed 6-22-05; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF STATE

22 CFR Part 62

RIN 1400-AC01

[Public Notice 5117]

Participation in the Exchange Visitor Program as Professor and Research Scholar; Correction

AGENCY: State Department.
ACTION: Correction to final rule.

SUMMARY: The Department of State published a document in the **Federal Register** of May 19, 2005, concerning a final rule on regulations for professors and research scholars in the Exchange Visitor Program. The document contained incorrect information regarding the 12-month bar, and this document corrects that error.

DATES: This correction becomes effective on the later of June 20, 2005, or the date upon which the Department of Homeland Security publishes a notice in the **Federal Register** announcing that it has completed the technical computer updates to its electronic Student and Exchange Visitor Information System (SEVIS) that are necessary to implement this rule.

FOR FURTHER INFORMATION CONTACT: Stanley S. Colvin, Office of Exchange Coordination, Bureau of Educational and Cultural Affairs, Department of State 202-203-5029; Fax 202-203-5087.

PART 62—[AMENDED]

■ 1. The authority citation for part 62 continues to read as follows:

Authority: 8 U.S.C. 1101(a)(15)(J), 1182, 1184, 1258; 22 U.S.C. 1431-1442, 2451-2460; Foreign Affairs Reform and Restructuring Act of 1998, Pub. L. 105-277, 112 Stat. 2681 *et seq.*; Reorganization Plan No. 2 of 1977, 3 CFR, 1977 Comp., p. 200; E.O. 12048 of March 27, 1978, 3 CFR, 1978 Comp., p. 168.

■ 2. Section 62.20 (d)(2) introductory text is revised to read as follows:

§ 62.20 Professors and research scholars.

* * * * *

(d) * * * (2) The participant has not been physically present in the United States as a nonimmigrant pursuant to the provisions of 8 U.S.C. 1101(a)(15)(J) for all or part of the twelve-month period immediately proceeding the date

of program commencement set forth on his or her Form DS-2019, unless:

* * * * *

Dated: June 17, 2005.
Stanley S. Colvin,
Director, Acting, Office of Exchange Coordination, Department of State.
 [FR Doc. 05-12456 Filed 6-22-05; 8:45 am]
BILLING CODE 4710-05-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9186]

RIN 1545-BD42

Qualified Amended Returns; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to temporary regulations (TD 9186) which were published in the **Federal Register** on Wednesday, March 2, 2005 (70 FR 10037). The temporary regulations modify the rules relating to qualified amended returns by providing additional circumstances that end the period within which a taxpayer may file an amended return that constitutes a qualified amended return.

DATES: This correction is effective March 2, 2005.

FOR FURTHER INFORMATION CONTACT: Nancy M. Galib at (202) 622-4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations (TD 9186) that are the subject of these corrections are under section 6227 of the Internal Revenue Code.

Need for Correction

As published, TD 9186 contains errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR Part 1 is corrected by making the following correcting amendments: