

TABLE I—INCREMENTAL PRICING ACQUISITION COST THRESHOLD PRICES

	January	February	March	April	May	June	July	August	September	October	November	December
Calendar Year 1984												
Incremental pricing threshold	\$2,263	\$2,291	\$2,299	\$2,307	\$2,315	\$2,323	\$2,331	\$2,338	\$2,345	\$2,352	\$2,359	\$2,366
NGPA Sec. 102 threshold	3,586	3,609	3,632	3,658	3,680	3,705	3,730	3,752	3,774	3,797	3,821	3,845
NGPA Sec. 109 threshold	2,359	2,367	2,375	2,383	2,391	2,399	2,407	2,414	2,421	2,428	2,436	2,444
130 pct. of No. 2 fuel oil in New York City threshold	7,730	7,570	7,570	8,550	8,590	7,670	7,930	7,740	7,650	7,230	7,040	7,290
Calendar Year 1985												
Incremental pricing threshold	\$2,373	\$2,378	\$2,383									
NGPA Sec. 102 threshold	3,689	3,690	3,911									
NGPA Sec. 109 threshold	2,452	2,457	2,462									
130 pct. of No. 2 fuel oil in New York City threshold	7,170	7,310	7,090									

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. 83-10]

Schedules of Controlled Substances;
Rescheduling of Buprenorphine From
Schedule II to Schedule V of the
Controlled Substances ActAGENCY: Drug Enforcement
Administration, Justice.

ACTION: Final rule.

SUMMARY: This is a final rule removing the drug buprenorphine from Schedule II and placing it in Schedule V of the Controlled Substances Act (CSA). Buprenorphine will continue to be classified as a narcotic controlled substance. This action was initiated after receipt by the Drug Enforcement Administration (DEA) of a letter from the Assistant Secretary for Health, Department of Health and Human Services (DHHS) recommending that buprenorphine be rescheduled to Schedule V concurrent with the approval by the Food and Drug Administration of a New Drug Application for buprenorphine. An approved New Drug Application is a prerequisite to the marketing of buprenorphine or any new drug in the United States. The effect of this rule is to retain Schedule V registration, recordkeeping and security requirements on those who import, export, manufacture, distribute, dispense, or conduct any activity with respect to buprenorphine. These requirements are the same as those required of any firm or individual handling any Schedule V narcotic controlled substance.

DATE: The effective date of this order is April 1, 1985.

FOR FURTHER INFORMATION CONTACT:

Gene R. Haislip, Deputy Assistant Administrator, Office of Division Control, Drug Enforcement Administration, Washington, D.C. 20537. Phone: (202) 633-1172.

SUPPLEMENTARY INFORMATION:

List of Subjects in 21 CFR Part 1308

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

On September 20, 1982, the then-Acting Administrator of the Drug Enforcement Administration issued a Notice of Proposed Rulemaking to amend § 1308.15 of Title 21 of the Code of Federal Regulations by placing buprenorphine in Schedule V as a narcotic controlled substance. 47 FR 41401. Buprenorphine was at that time a Schedule II narcotic controlled substance by virtue of being a derivative of opium or an opiate. The scheduling action was initiated following receipt of a letter dated May 12, 1982 from the Assistant Secretary of Health on behalf of the Secretary, Department of Health and Human Services to the then-Acting Administrator of DEA. The letter notified DEA that the Food and Drug Administration had approved a New Drug Application for buprenorphine, an analgesic drug with a potential for abuse. The DHHS recommended that buprenorphine be rescheduled into Schedule V and that the drug continue to be classified as a narcotic because it is a derivative of the opiate thebaine. The DHHS reported in its findings that buprenorphine has a low potential for abuse relative to the drugs in Schedule IV, that it has a currently accepted medical use in treatment in the United States, and that abuse of buprenorphine may lead to limited physical dependence or psychological dependence relative to other drugs in Schedule IV. The Notice of Proposed Rulemaking allowed sixty days for interested parties to submit comments, objections, or requests for a hearing. On

November 11, 1982, Reckitt and Colman Ltd., the patent holder for buprenorphine, filed a request for a hearing objecting to both continued control of buprenorphine under any CSA schedule and to classification of the drug as a narcotic. McNeil Pharmaceuticals, a major manufacturer of analgesics, also requested a hearing. In response to the requests for hearing, and having found that issues had been raised which warranted a hearing, the Acting Deputy Administrator of the Drug Enforcement Administration requested that the Agency's Administrative Law Judge convene a hearing for the purpose of receiving evidence and reporting his findings, conclusions, and other recommendations to the Administrator of DEA. The proceeding was conducted "on the record after opportunity for a hearing" as required by 21 U.S.C. 811(a) and in accordance with the Administrative Procedure Act. 5 U.S.C. 556 and 557.

The authority and criteria for classifying substances into schedules under the Controlled Substances Act is found in 21 U.S.C. 811. This section of the Act sets forth the standards by which the Attorney General and the Secretary of the Department of Health and Human Services are to evaluate substances for control or decontrol. The Secretary of DHHS is charged with making scientific and medical evaluations, including scientific evidence of a substance's pharmacological effects, the state of current scientific knowledge regarding the drug or other substance, what risk there is to the public health, the psychic or physiological dependence liability of the drug, and whether the substance is an immediate precursor of a substance already controlled under the Act. The Attorney General must consider those items presented by the Secretary, and in addition must consider the actual or relative potential for abuse of the substance, the history and current pattern of abuse, and the scope,

duration and significance of abuse. Buprenorphine was in Schedule II of the CSA by virtue of its derivation from thebaine. The substance had not been approved for marketing in the United States by the Food and Drug Administration until 1982. It was however, marketed in 28 countries in Europe and Australasia prior to 1982.

Four hearing sessions, comprising 13 hearing days, were conducted before the Administrative Law Judge. On October 24, 1984, the judge issued his Opinion and Recommendations regarding the rescheduling of buprenorphine. The judge recommended that buprenorphine not be controlled under the CSA, and that the drug not be defined as a narcotic. The judge presented two main reasons for the decontrolling of buprenorphine under the CSA. With respect to evidence of abuse of buprenorphine in Australia, New Zealand and West Germany, the judge characterized activities in those countries, including evidence of theft, prescription forgery, and a black market for buprenorphine, as misuse rather than abuse, and pointed out that there was no evidence presented of abuse or misuse in more than a few of the countries where the drug is marketed. As a second basis for not scheduling buprenorphine under the CSA, the judge concluded that control of buprenorphine would inhibit availability of the drug for legitimate medical purposes. The judge indicated that buprenorphine is a drug for the treatment of moderate to severe pain and that physicians might be hesitant to prescribe the drug and patients may suffer thereby. He also noted that two similar drugs, nalbuphine and butorphanol are not controlled and he also distinguished buprenorphine from pentazocine, another similar drug which is controlled in Schedule IV of the CSA. All four of these substances, buprenorphine, nalbuphine, butorphanol, and pentazocine, are considered analgesics and opiate agonist-antagonist substances. The judge also concluded and recommended to the Administrator that buprenorphine should not be classified as a narcotic drug. The judge then recommended that the Administrator adopt a rather narrow definition of derivative, and that using such definition, buprenorphine would not be a derivative of thebaine. He found that buprenorphine was not a derivative of thebaine because there are six or possibly seven steps required in the chemical transportation from thebaine to buprenorphine and some of these steps are relatively complex. He also noted that using the general definition of derivative, aspirin can be

considered a derivative of thebaine since it can be produced from thebaine. The judge concluded that buprenorphine is too chemically remote from thebaine to be termed a derivative, and therefore that buprenorphine is not a narcotic.

On November 13, 1984, counsel for DEA and McNeil Pharmaceuticals filed exceptions to the Opinion and Recommendations of the Administrative Law Judge. In reply, Reckitt and Colman filed a Response to the exceptions on December 7, 1984. On December 13, 1984, the Administrative Law Judge certified and transmitted the record to the Administrator of DEA. The record included the Opinion and Recommendations of the Administrative Law Judge, the findings of fact and conclusions of law proposed by all parties, the exceptions filed by counsel for DEA and McNeil Pharmaceuticals, the response to those exceptions filed by Reckitt and Colman, all of the exhibits and affidavits, and all of the transcripts of the hearing sessions.

The Administrator has carefully reviewed the entire record in this matter and hereby issues this final rule as prescribed by 21 CFR 1316.67. The Administrator declines to accept the recommendations of the Administrative Law Judge and finds that there is substantial evidence in the record to support the decision that buprenorphine be placed in Schedule V as a narcotic drug. The Administrator finds, consistent with his decision that:

1. Buprenorphine has a low potential for abuse relative to the drugs or other substances in Schedule IV.
2. Buprenorphine has a currently accepted medical use in treatment in the United States.
3. Abuse of buprenorphine may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.

In support of the above listed findings, the Administrator makes the following specific factual findings:

1. Buprenorphine is an analgesic, agonist-antagonist drug.
2. Buprenorphine is a morphine-like drug that is 25 to 50 times more potent than morphine and is longer acting.
3. Buprenorphine, in human testing, has been found to have a "mood elevating" effect, and to produce other morphine-like effects, including "euphoria."
4. Buprenorphine has been approved by the Food and Drug Administration for treatment of moderate to severe pain.
5. Animal studies with buprenorphine indicate that rats will spontaneously

initiate self-administration of buprenorphine, although at a lower rate than they will self-administer codeine, a Schedule III narcotic controlled substance.

6. Buprenorphine was recognized as an opiate in animal studies in which rats were trained to discriminate fentanyl, a Schedule II opiate from saline.

7. In human tests utilizing buprenorphine, morphine and a placebo, buprenorphine was identified as an opiate by both subjects and observers.

8. In the scheduling recommendation the Assistant Secretary of Health, Department of Health and Human Services recommended narcotic classification for buprenorphine "based on the chemical derivation of buprenorphine from thebaine, an opium constituent."

9. The thebaine ring skeleton and structure are contained within the structure of buprenorphine.

10. Thebaine is converted to buprenorphine through the Diels-Alder adduct of thebaine. The conversion of the Diels-Alder adduct of thebaine to buprenorphine is by way of standard chemical reactions.

11. The developer of buprenorphine described buprenorphine as a thebaine derivative.

12. *Van Nostrand's Scientific Encyclopedia*, 5th Ed. defines derivative as:

A term used in organic chemistry to express the relation between certain known or hypothetical substances and the compound formed from them by simple chemical processes in which the nucleus or skeleton of the parent substance exists. Usually the term applies to those compounds where the resulting compound is formed in one step, although a chain of steps may be involved in some cases depending essentially upon how easy it is to identify the "derivative" within the parent substance. Where a chain of steps is involved, the intervening compounds often are called "intermediates" rather than "derivatives."

13. There are four agonist-antagonist analgesics approved for marketing in the United States; buprenorphine, butorphanol, nalbuphine, and pentazocine.

14. Pentazocine and buprenorphine are both centrally acting analgesics having antagonistic properties and act at the mu and kappa receptors of the brain.

15. Pentazocine was controlled under the CSA in Schedule IV in 1978 after evidence of its widespread abuse in the United States was documented.

16. Buprenorphine is currently marketed in 28 countries in Europe and

Australasia under the trade name Temgesic.

17. Buprenorphine was initially marketed in Australia in its injectable form in November, 1982.

18. Buprenorphine was not approved in Australia for treatment of opiate addiction.

19. By October, 1983, 97 registered addicts in Australia received prescriptions for buprenorphine in Western Australia.

20. In early 1984, an illicit market for buprenorphine developed in Western Australia where ampules of buprenorphine were selling for \$20 to \$50 Australian each. (U.S. equivalent \$.90 per Australian dollar at that time)

21. Buprenorphine, in its injectable form, was approved for marketing in New Zealand in May, 1979. The oral formulation was approved for use in New Zealand in April, 1981.

22. From August, 1982 to December, 1982 the Auckland Hospital Outpatient Pharmacy in New Zealand filled 667 prescriptions for oral buprenorphine, 27% were for known or suspected drug abusers.

23. The New Zealand Department of Health received information that through July 31, 1983, there had been at least 280 instances of known drug abusers visiting doctors and specifically seeking buprenorphine.

24. Many prescription alterations and forgeries of buprenorphine prescriptions were reported in New Zealand for the period up to July, 1983.

25. On September 5, 1983, buprenorphine became a controlled drug in New Zealand.

26. In Christchurch, New Zealand buprenorphine tablets were selling for between NZ \$10 and NZ \$15 per tablet. (U.S. equivalent \$.64 per New Zealand dollar at that time)

27. Buprenorphine was approved for marketing in the Federal Republic of Germany (West Germany) in injectable form in February, 1981, and in oral, sublingual form in May, 1983.

28. By June 24, 1983, the Federal German Office of Criminal Investigation had received reports of 142 known instances of illegal obtaining of buprenorphine, from a total of 168 buprenorphine-related offenses. Of the 168 reported offenses, 131 involved prescription falsification and 24 involved theft and/or criminal conversion.

29. For the year 1983, the total number of buprenorphine-related criminal incidents reported to the Federal German Office of Criminal Investigation was 336.

30. In February, 1983 there was an armed robbery of a pharmacy in West

Germany where the robber demanded only Temgesic, the brand name for buprenorphine. In all of 1982 there were only 35 armed robberies of pharmacies in all of West Germany.

31. In Munich, West Germany, an individual diverted 300 packages of buprenorphine from a wholesaler. This individual was himself subsequently robbed by force of the buprenorphine.

32. A black market for buprenorphine has developed in southern West Germany.

33. As of March, 1984 there have been 130 documented cases of buprenorphine abusers in West Germany. Seventy percent of these abusers were street drug abusers and 27% were those who abused medical drugs.

34. On March 7, 1984, the West German Narcotic Advisory Council recommended to the West German government that buprenorphine be controlled.

35. As of March, 1984 buprenorphine had not been approved for marketing in Italy.

36. In December, 1982 a physician in northwestern Italy who treats drug dependent patients reported many patients taking buprenorphine. The physician reported the drug was being obtained in Switzerland via prescription.

37. Heroin addicts in Genoa, Italy were using buprenorphine obtained by prescriptions filled in Swiss pharmacies as a heroin substitute. These individuals were using 10 to 30 vials of buprenorphine a day.

38. At the insistence of an Italian National Police authority in Genoa, a Swiss official circulated an order to Swiss pharmacists along the Italian border directing them not to fill prescriptions written by Italian doctors.

39. On August 21, 1983, the Italian Ministry of Health placed buprenorphine in Table IV of the Narcotic Act. Illegal distribution of a Table IV drug is subject to substantial criminal penalties including fines and imprisonment.

Evidence of abuse of buprenorphine is well documented in Australia, New Zealand, West Germany and Italy. Although characterized by the Administrative Law Judge in his Opinion as primarily "misuse" as opposed to "abuse", the Administrator finds the activity described in the record was most assuredly "abuse." The Administrative Law Judge described "misuse" as use of a drug in a manner not approved by medical authorities. Evidence adduced in the course of these proceedings showed that individuals were seeking buprenorphine as a morphine or heroin substitute. They

were seeking the drug for its euphorogenic effects. They were seeking it not to ameliorate the pain from surgery, injury or illness, but to forestall the onset of narcotic withdrawal symptoms.

Addicts and drug abusers of all descriptions commonly attempt to obtain prescriptions for controlled substances by "duping" physicians with seemingly legitimate complaints. In the United States, this method is often used to obtain narcotics, depressants and stimulants. In West Germany and New Zealand, it was also used to obtain buprenorphine. Addicts in New Zealand sought buprenorphine tablets which they then dissolved in water and injected intravenously. This is not misuse. This activity is precisely what the Administrator has come to know as diversion of legitimately produced drugs for purposes of their subsequent abuse. The evidence in this case described burglaries and armed robberies in which buprenorphine was the targeted drug. The forgery and alteration of buprenorphine prescriptions was reported as was a black market for buprenorphine tablets. These activities provide substantial evidence that buprenorphine not only has a potential for abuse, but that it is actually being abused and has developed a following among addicts and abusers. The pattern of abuse of buprenorphine in Europe and Australasia is identical to the pattern of abuse for other legitimately produced pharmaceuticals in the United States. As a result of this abuse of buprenorphine the drug has become controlled in New Zealand and Italy and has been proposed for control by West German authorities. The Administrator finds that the rapid onset of significant abuse of buprenorphine in these Western countries is of particular importance with respect to his decision to retain some controls on buprenorphine in the United States. The potential for abuse of buprenorphine is evident from its pharmacological properties and the fact that it does produce physical and psychological dependence. Buprenorphine's morphine-like effects are mentioned throughout the record in this proceeding. The drug seeking behavior of documented drug abusers in the countries where the drug is marketed reinforces this statement.

The Administrative Law Judge placed great weight on the fact that two drugs with properties similar to buprenorphine are not currently controlled under the CSA. The Administrator finds that the fact that butorphanol and nalbuphine are not currently classified as controlled substances carries little if any weight in

this proceeding. The scheduling of these two substances is not at issue in this matter. At such time as evidence of abuse of butorphanol and nalbuphine are presented to DEA, they will be specifically evaluated for control under the CSA.

Control of a legitimately marketed pharmaceutical drug may have some effect on the decision of a physician to prescribe that drug. There may be some physicians who are reluctant to prescribe any controlled substance. However, the Administrator notes that oral codeine analgesics are among the most widely prescribed drugs in this country. These drugs are classified as Schedules II and III narcotics. If such classification has not deterred physicians from prescribing those drugs, the Administrator finds it difficult to understand how one can seriously contend that Schedule V controls will somehow deter legitimate prescribing of buprenorphine. The proper prescribing of drugs is a question of medical practice. The placing of a drug in Schedule V will alert a physician that the drug does cause limited physical and psychological dependence. This is valuable information for a physician to possess before prescribing any drug. The Administrative Law Judge in his Opinion and Recommendations refers to the "real world" where physicians may be unwilling to prescribe a controlled substance. The Administrator notes that the "real world" includes the fact of drug abuse, and the recognition that a large population of individuals in the United States abuse all types of drugs. The Administrator also recognizes that the drug abuse problem is related to crime and other societal problems. The Administrator has a duty to protect the public health and safety. He concludes that the potential for abuse of buprenorphine far outweighs any potential reluctance on the part of a physician to prescribe a drug as pain medication. In conclusion, the Administrator finds that buprenorphine has a potential for abuse sufficient to warrant its control in Schedule V of the Controlled Substances Act. There is substantial evidence of actual abuse of buprenorphine in foreign countries, as well as potential for abuse in the United States. The public health and safety demands that control of this drug be retained.

The Administrator recognizes that designating a drug as a narcotic does have regulatory and possible international drug control ramifications. As the judge noted in his Opinion, a narcotic controlled substance requires an import permit and special findings

with respect to medical need and adequacy of domestic supply for each importation. Prescriptions may not be issued for a narcotic for purposes of maintenance or detoxification treatment. However, there are many pharmaceuticals controlled as Schedule V narcotics in the United States which are regularly prescribed and dispensed for medical purposes and such controls do not deter their legitimate use.

Prior to the initiation of this control action DEA considered buprenorphine a narcotic drug because of its derivation from opium through the alkaloid thebaine. Buprenorphine is produced from thebaine in seven common and well-documented chemical steps which result in a structure with a ring skeleton much like that of morphine and heroin, which in turn resembles that of thebaine. Even though there are seven chemical steps in the reaction sequence, it is the first step which establishes the ring skeleton system of buprenorphine. To attribute great significance to the actual number of chemical steps is misleading. The subsequent chemical reactions involve minor additions and substitutions to this first "derivative."

The Administrator acknowledges that the term "derivative" is not defined in the CSA or implementing regulations. DEA and the Food and Drug Administration have consistently treated substances produced from thebaine as narcotics. FDA recommended narcotic classification for buprenorphine based on the fact that buprenorphine is derived from the opium constituent thebaine. Although authorities disagree, the reactions which produce buprenorphine from thebaine conform to the definition of derivative in recognized chemical literature. The Administrative Law Judge noted in his Opinion that aspirin can also be produced from thebaine. This is an absurd and impractical extension of the concept of derivative. There is a middle ground between a narrow precise definition and such an all-encompassing definition. Not only can buprenorphine be characterized as a derivative of thebaine and therefore a narcotic by chemical definition, the evidence in the record of this proceeding clearly shows that the narcotic drug abuser, and even the heroin addict, recognizes buprenorphine as a narcotic. Such evidence was presented from countries where the drug has only been marketed for a few years.

The Administrator finds that there is substantial evidence in the record to support his conclusion that buprenorphine is a narcotic drug. It is quite clear that addicts recognize

buprenorphine as a narcotic and utilize it as a heroin substitute. They clearly understand that buprenorphine is not aspirin or acetaminophen. Buprenorphine possesses sufficient opiate-like actions and does so resemble the structure of its parent, thebaine, that it must be considered to be a derivative thereof, and therefore classified as a narcotic within the meaning of the Controlled Substances Act.

Placement of a substance into Schedule V and designating it as a narcotic imposes certain regulatory requirements on those handling the substance. These requirements are less stringent than those currently imposed on buprenorphine by virtue of its classification as a Schedule II narcotic. Regulatory requirements imposed by the CSA and implementing regulations are effective on April 1, 1985. The regulatory requirements imposed on those handling buprenorphine on the effective date are as follows:

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports buprenorphine or who proposes to engage in such activities, if not already registered, shall submit any application for registration to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations on or before April 1, 1985.

2. *Security.* Buprenorphine must be manufactured, distributed, and stored in accordance with §§ 1301.71, 1301.72(b)-(d), 1301.73, 1301.74(a)-(f), 1301.75(b)-(c), and 1301.76 of Title 21 Code of Federal Regulations.

3. *Labeling and packaging.* All labels on commercial containers of, and all labeling of buprenorphine packaged after April 1, 1985, shall 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 who is required to keep records and who possesses any quantity of buprenorphine is required to take inventories pursuant to § 1304.04 and §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations.

5. *Records.* All registrants must keep records of buprenorphine pursuant to §§ 1304.21-1304.27 of Title 21 of the Code of Federal Regulations.

6. *Prescriptions.* The Food and Drug Administration has approved buprenorphine as a prescription drug. Accordingly, all prescriptions for buprenorphine shall comply with §§ 1306.01-1306.07 and §§ 1306.26-1306.31 of Title 21 of the Code of Federal Regulations.

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

8. *Criminal liability.* Any activity with buprenorphine not authorized by or in violation of the Controlled Substances Act or the Controlled Substances Import and Export Act continues to be unlawful. The applicable penalties before April 1, 1985, shall be those of a Schedule II narcotic controlled substance. After that date the criminal penalties shall be those of a Schedule V narcotic.

9. *Other.* In all other respects, this Order is effective April 1, 1985.

Pursuant to Title 5, United States Code, section 605(b), the Administrator certifies that the rescheduling of buprenorphine, as ordered herein, 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). The vast majority of pharmaceutical firms, hospitals, pharmacies, and physicians are already registered by DEA to handle Schedule V controlled substances.

In accordance with the provisions of section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)), this scheduling action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to provisions of the Administrative Procedure Act, 5 U.S.C. 556 and 557 and as such have been exempted from the consultation requirements of Executive Order 12291 (46 FR 13193).

Under the authority vested in the Attorney General by section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)) and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice, 28 CFR 0.100(b), the Administrator hereby orders that Part 1308, Title 21, Code of Federal Regulations be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

The authority citation for Part 1308 reads as follows:

Authority: Secs. 201, 202, 501(b), 84 Stat. 1245, 1246, 1247, 1248, 1249, 1250, 1251, 1252, 1271, 21 U.S.C. 811, 812, 871(b).

1. Paragraph (b) of 21 CFR 1308.15 is redesignated as paragraph (c).

2. New paragraph (b) entitled Narcotic drugs is added to 21 CFR 1308.15 to read as follows:

§ 1308.15 Schedule V

(b) *Narcotic drugs.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts, as set forth below:

(1) Buprenorphine.....9064

Dated: February 26, 1985.

Francis M. Mullen, Jr.,
Administrator.

[FR Doc. 85-4989 Filed 2-27-85; 8:45 am]

BILLING CODE 4410-09-M

INTERNATIONAL DEVELOPMENT AND COOPERATION AGENCY

Agency for International Development

22 CFR Part 218

Non-Discrimination on the Basis of Age in Programs Receiving Federal Financial Assistance

AGENCY: Agency for International Development.

ACTION: Final rule; correction.

SUMMARY: This document corrects a legal citation contained in the final regulations implementing provisions of the Age Discrimination Act of 1975.

FOR FURTHER INFORMATION CONTACT: Nancy D. Frame, Assistant General Counsel for Employee and Public Affairs, Agency for International Development, Washington, D.C. 20523 (202) 632-8218.

Accordingly, in FR Doc. 80-2301, appearing at page 62979 in the issue of September 23, 1980, the authority citation which appears just after the table of contents for Part 218 on page 62980 is corrected to read as follows:

Authority: Age Discrimination Act of 1975, as amended, 42 U.S.C. 6101 et seq.; 45 CFR Part 90; 22 U.S.C. 2658.

Nancy D. Frame,
Assistant General Counsel, Employee and Public Affairs.

[FR Doc. 85-4750 Filed 2-27-85; 8:45 am]

BILLING CODE 6116-01-M

22 CFR Part 221

Employment

AGENCY: Agency for International Development.

ACTION: Final rule; revocation.

SUMMARY: Part 221 of this title was issued to proscribe regulations relating to employment and tours of assignment of AID Foreign Service Employees. The

enactment of the Foreign Service Act of 1980 renders part 221 of Title 22 CFR obsolete and it is therefore being revoked.

EFFECTIVE DATE: April 1, 1985.

FOR FURTHER INFORMATION CONTACT: Nancy D. Frame, Assistant General Counsel for Employee and Public Affairs, Agency for International Development, Washington, D.C. 20523 (202) 632-8218.

List of Subjects in 22 CFR Part 221

Foreign Service.

PART 221—[REMOVED]

Accordingly, 22 CFR Part 221 is removed.

(Sec. 401, International Development and Food Assistance Act of 1978, Pub. L. 95-424, 92 Stat. 956, as amended by sec. 503, International Development Cooperation Act of 1979, Pub. L. 96-53, 93 Stat. 378)

Nancy D. Frame,
Assistant General Counsel, Employee and Public Affairs.

[FR Doc. 85-4756 Filed 2-27-85; 8:45 am]

BILLING CODE 6116-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 950

Approval of Permanent Program Amendment From the State of Wyoming Under the Surface Mining Control and Reclamation Act of 1977

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule.

SUMMARY: OSM is announcing the approval of a program amendment submitted by Wyoming as an amendment to the State's permanent regulatory program (hereinafter referred to as the Wyoming program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment establishes procedures and requirements governing operator responsibility when requesting a variance from program standards and the State's responsibility in processing such requests, provisions for self-bonding and provisions addressing inspection, enforcement and civil penalties for surface coal mining operations. Wyoming submitted the proposed program amendment on June 25, 1984. OSM published a notice in the July 25, 1984 Federal Register,

announcing receipt of the amendment and inviting public comment on the adequacy of the proposed amendment (49 FR 29807). The public comment period closed August 23, 1984. After review of the proposed material, OSM on October 2, 1984, notified Wyoming of several identified concerns. On November 1, 1984, Wyoming submitted additional clarifying material addressing OSM's concerns. OSM announced receipt of the material in the January 14, 1985 Federal Register (50 FR 1869) and reopened the comment period until January 29, 1985.

After providing opportunity for public comment and conducting a thorough review of the program amendment, the Director has determined that the amendment meets the requirements of SMCRA and the Federal regulations, and is approving it. The Federal rules at 30 CFR Part 950 codifying decisions concerning the Wyoming program are being amended to implement this action.

This final rule is being made effective immediately in order to expedite the State program amendment process and encourage States to conform their programs to the Federal standards without delay; consistency of the State and Federal standards is required by SMCRA.

EFFECTIVE DATE: February 28, 1985.

FOR FURTHER INFORMATION CONTACT: Mr. William R. Thomas, Director, Casper Field Office, Office of Surface Mining, Freden Building, 935 Pendell Boulevard, Mills, Wyoming 82644; Telephone: (307) 261-5776.

SUPPLEMENTARY INFORMATION:

I. Background

The Wyoming program was conditionally approved by the Secretary of the Interior on November 26, 1980 (45 FR 78637-78634). Information pertinent to the general background, revisions, modifications, and amendments to the proposed permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval of the Wyoming program can be found in the November 26, 1980 Federal Register (45 FR 78637), the February 18, 1982 Federal Register (47 FR 7218), the September 27, 1982 Federal Register (47 FR 42351) and the November 9, 1983 Federal Register (48 FR 51465).

II. Submission of Revisions

On June 25, 1984, Wyoming submitted to OSM a program amendment that addresses procedures to be followed by operators when requesting approval by the State to conduct experimental

practices on surface coal mining operations, provisions for self-bonding and provisions for inspection, enforcement and civil penalty assessments for surface coal mining operations. The July 25, 1984 Federal Register (49 FR 1869) announced receipt of the materials and opened the initial comment period. In the same notice, OSM announced that a public hearing would be held only if requested. No requests were received and no hearing was held. A review by OSM identified minor deficiencies in the Wyoming submission. The State was notified October 2, 1984, of OSM's concerns and subsequently provided clarifying material on November 1, 1984. OSM announced receipt of the new material in the January 14, 1985 Federal Register (50 FR 1864) and reopened the public comment period until January 29, 1985. No additional comments were received.

III. Director's Findings

In accordance with SMCRA and 30 CFR 732.15 and 732.17, the Director finds that the revised program amendment to the Wyoming Land Quality Division Rules as submitted by Wyoming on June 25, 1985, and clarified on November 1, 1984, meets the requirements of SMCRA and 30 CFR Chapter VII, as discussed below.

A. Chapter IX Variances for Surface Coal Mining Operations

Wyoming has revised this section so that it implements the revised provisions of 30 CFR 785.13 which address both operator responsibility when requesting approval of variances from program standards and the State regulatory authorities' responsibility in processing such requests. The amendment consists of revised regulations addressing the required contents of an operator's request for a variance and procedures to be followed by both the applicant and the Wyoming Land Quality Division in processing requests for variances. In its October 2, 1984 letter to Wyoming, OSM identified the following concern:

Wyoming did not provide evidence that the Administrator, Land Quality Division had authority to require modifications of experimental practices, as necessary, to ensure full protection of the environment and public health and safety. Wyoming, in its November 1, 1984 correspondence, responded to OSM's concern by pointing out that applicants must conduct special monitoring with respect to experimental practices as required at Section 1a(2)(b)(iii), Chapter IX, so as to assure protection of the environment and public health and safety. Wyoming also stated that the Administrator, Land Quality Division is required to review annually all experimental practices and has authorized to require an operator to abandon an

experimental practice if protection of the environment and public safety can not be assured. Wyoming stated that if the Administrator has such authority, it is assumed he has authority to require less drastic measures such as requiring modifications of experimental practices. The Director agrees with Wyoming's explanation and finds that these changes are no less effective than Federal regulations at 30 CFR 785.13.

B. Chapter XII Self-Bonding Program

Wyoming has revised this section so that it implements the revised provisions of 30 CFR Part 800 which address self-bonding. This amendment consists of proposed regulations containing new and revised definitions relative to bonding application requirements for operators interested in self-bonding, methods for renewing bonds filed under the self-bonding program, procedures to be followed by the regulatory authority for processing and acting upon an operator's application to self-bond, provisions for the regulatory authority to require the substitution of a self-bond if it finds the operator's self-bond does not provide adequate protection, procedures for both the release and forfeiture of an operator's self-bond, and procedures for self-bonding existing operators. The Director finds that these changes are no less effective than the Federal regulations at 30 CFR Part 800 and do not render this section less stringent than section 509 of SMCRA.

C. Chapter XVII Inspection, Enforcement and Penalties for Surface Coal Mining Operations

Wyoming has revised this section so that it implements the revised provisions of 30 CFR Parts 840 and 845 which address inspection, enforcement and civil penalty assessment for surface coal mining operations. This amendment consists of regulations addressing both the frequency and extent of inspections on active and inactive surface coal mining operations, minimum content requirements for the following enforcement documents: cessation orders, notice of abatement and order to show cause, administrative procedures for handling enforcement actions and procedures for assessing and processing civil penalties.

In its October 2, 1984, letter to Wyoming, OSM identified the following concerns:

(1) Wyoming did not provide language consistent with 30 CFR 842.11(b)(1)(i) which provides complainants an opportunity to allege to the State that certain conditions or practices exist which create a danger to public health and safety or cause imminent environmental harm. Wyoming responded in

its November 1, 1984 correspondence that Section 1a (1) and (2), Chapter XVII not only provides complainants an opportunity to allege that the State has failed to comply with inspection frequency requirements but also allows complainants to allege that the State has failed to inspect a site immediately to enforce the act, regulations or any permit condition.

(2) Wyoming failed at Chapter XVII to address the right of persons supplying information to the regulatory authority relating to possible violations to remain confidential if so desired. In its November 1, 1984 response, Wyoming indicated that confidentiality would be provided to a complainant, if requested, under section 16-4-203(a)(ii) of the Wyoming Public Records Law, a copy of which was provided to OSM.

(3) While Wyoming provides for notification of a pending mine inspection to a complainant whose allegation or information is the basis for the inspection at Section 1e, Chapter XVII, it failed to provide that such notification would be provided as far in advance as practicable. Wyoming stated in the November 1, 1984, response that, while the proposed rule does not contain language which specifically states that such notification will occur as far in advance as practicable, it is reasonable to assume that the Director will do so in the discharge of his normal duties.

(4) Wyoming's standard for issuance of a show cause order at Section 2e(1)(a), Chapter XVII is narrower than the Federal standard at 30 CFR 843.5. The Federal standard for a willful violation is that it be committed by a person who intends the result that actually occurs. The Wyoming standard for willful violation is that the violation be committed by a person who knows, or has reason to know, the act is unlawful. The Federal standard requires intent but does not require knowledge. Wyoming indicated that this particular provision was not revised from that which was approved by the Secretary of the Interior in his Finding 20.F published in the November 26, 1980 Federal Register notice (45 FR 78872). The Director is reserving the right to reevaluate this provision as part of OSM's regulatory reform effort.

The Director concurs with Wyoming's November 1, 1984 explanations and response to OSM's concerns and finds that those changes are consistent with Federal regulations at 30 CFR Parts 840 and 845 and do not render this section less stringent than sections 517, 518 and 521 of SMCRA.

IV. Public Comments

Pursuant to section 503(b) of SMCRA and 30 CFR 732.17(h)(10)(i), of those Federal agencies invited to comment, none chose to do so. No additional public comments were received.

The disclosure of Federal agency comments is made pursuant to section 503(b) of SMCRA and 30 CFR 732.17(h)(10)(i).

V. Director's Decision

The Director, based on the above findings, is approving the amendment to the Wyoming program submitted on June 25, 1984, and as clarified by the State on November 1, 1984. The Director is amending Part 950 of 30 CFR Chapter VII to reflect approval of the above State program modification.

VI. Procedural Requirements

1. *Compliance with the National Environmental Policy Act:* The Secretary has determined that, pursuant to section 702(d) of SMCRA, 30 U.S.C. 1292(d), no environmental impact statement need be prepared on this rulemaking.

2. *Executive Order No. 12291 and the Regulatory Flexibility Act:* On August 28, 1981, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Therefore, this action is exempted from preparation of a Regulatory Impact Analysis and regulatory review by OMB.

The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule will not impose any new requirements; rather, it will ensure that existing requirements established by SMCRA and the Federal rules will be met by the State.

3. *Paperwork Reduction Act:* This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507.

List of Subjects in 30 CFR Part 950

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Authority: Pub. L. 95-87, Surface Mining Control and Reclamation Act of 1977 (30 U.S.C. 1201 *et seq.*).

Dated: February 22, 1985.

John D. Ward,
Director, Office of Surface Mining.

PART 950—WYOMING

30 CFR 950.15 is amended by adding a new paragraph (d) as follows.

§ 950.15 Approval of regulatory program amendments.

(d) The following amendment submitted to OSM on June 25, 1984, and clarified by the State on November 1, 1984, is approved effective February 28,

1985: Wyoming's regulations governing operator responsibility when requesting a variance from program standards and the State's responsibility in processing such a request at Sections 1 and 2 respectively, Chapter IV of the Wyoming Land Quality Division (LQD) Rules and Regulations; definitions relating to self-bonding at Section 1, Chapter XII of the LQD rules, procedures to be followed by an applicant when applying for self-bonding provisions at Section 2, Chapter XII of the LQD rules, procedures to be followed by an operator in the process of renewing an existing bond with a self-bond at Section 3, Chapter XII of the LQD rules; procedures to be followed by the State regulatory authority in approving or denying an operators request to self-bond at Section 4, Chapter XII of the LQD rules; procedures to be followed by the State regulatory authority when requiring an operator to replace a questionable self-bond with a substitute form of bond at Section 5, Chapter XII of the LQD rules; requirements addressing the release or forfeiture of self-bonds at Section 6, Chapter XII of the LQD rules; requirements for operators of existing operations to follow in substituting self-bonds for other forms of bond at Section 7, Chapter XII of the LQD rules; frequency and extent of mine inspections at Section 1, Chapter XVII of the LQD rules; procedures to be followed in handling enforcement actions at Section 2, Chapter XVII of the LQD rules, and procedures to be followed by the State regulatory authority in assessing civil penalties at Section 3 Chapter XVII of the LQD rules. [FR Doc. 85-4890 Filed 2-27-85; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Paducah, KY; Regulation 85-01]

Safety Zone Regulations; Ohio River Mile 960-965

AGENCY: Coast Guard, DOT.

ACTION: Emergency rule.

SUMMARY: The Coast Guard is establishing a safety zone between Mile 960 and 965, Ohio River.

The zone is needed to protect divers and rescue personnel from a safety hazard associated with a towboat sunk in the channel. Entry into this zone is