(4) Earthquake;
(5) Volcanic eruption; or
(6) Failure of the irrigation water supply, if caused by an insured peril that occurs during the insurance period.
(b) In addition to the causes of loss excluded in section 12 (Causes of Loss) of the Basic Provisions (§ 457.8), we will not insure against damage or loss of production due to:
(1) Disease or insect infestation, unless adverse weather:
(i) Prevents the proper application of control measures or causes properly applied control measures to be ineffective; or
(ii) Causes disease or insect infestation for which no effective control mechanism is available; or
(2) Inability to market the prunes for any reason other than actual physical damage from an insurable cause specified in this section. For example, we will not pay you an indemnity if you are unable to market due to quarantine, boycott, or refusal of any person to accept production.

10. Duties in the Event of Damage or Loss

In addition to the requirements of section 14 (Duties in the Event of Damage or Loss) of the Basic Provisions (§ 457.8), the following will apply:
(a) You must notify us within 3 days of the date harvest should have started if the crop will not be harvested.
(b) You must notify us at least 15 days before any production from any unit will be sold by direct marketing or sold as fresh fruit. We will conduct an appraisal that will be used to determine your production to count for production that is sold by direct marketing or is sold as fresh fruit production. If damage occurs after this appraisal, we will conduct an additional appraisal. These appraisals, and any acceptable records provided by you, will be used to determine your production to count. Failure to give timely notice that production will be sold by direct marketing or sold as fresh fruit will result in an appraised amount of production to count of not less than the production guarantee per acre if such failure results in our inability to make the required appraisal.
(c) If you intend to claim an indemnity on any unit, you must notify us at least 15 days prior to the beginning of harvest or immediately if damage is discovered during harvest, so that we may inspect the damaged production.
(d) You must not destroy the damaged crop until after we have given you written consent to do so. If you fail to meet the requirements of this section and such failure results in our inability to inspect the damaged production, all such production will be considered undamaged and included as production to count.

11. Settlement of Claim

(a) We will determine your loss on a unit basis. In the event you are unable to provide separate acceptable production records:
(1) For any optional unit, we will combine all optional units for which such production records were not provided; or
(2) For any basic units, we will allocate any commingled production to such units in proportion to our liability on the harvested acreage for each unit.
(b) In the event of loss or damage covered by this policy, we will settle your claim by:
(1) Multiplying the insured acreage for each varietal group, if applicable, by its respective production guarantee;
(2) Multiplying the result in 11(b)(1) by the respective price election for each varietal group, if applicable;
(3) Totaling the results in section 11(b)(2);
(4) Multiplying the total production to be counted of each varietal group, if applicable, (see sections 11 (c) through (e)) by the respective price election;
(5) Totaling the results in section 11(b)(4);
(6) Subtracting the result in section 11(b)(5) from the result in section 11(b)(3); and
(7) Multiplying the result in section 11(b)(6) by your share.
(c) The total production to count (in tons) from all insurable acreage on the unit will include all harvested and appraised production of natural condition prunes that grade substandard or better and any production that is harvested and intended for use as fresh fruit. The total production to count will include:
(1) All appraised production as follows:
(i) Not less than the production guarantee per acre for acreage:
(A) That is abandoned;
(B) That is sold by direct marketing or sold as fresh fruit if you fail to meet the requirements contained in section 10;
(C) That is damaged solely by uninsured causes; or
(D) For which you fail to provide acceptable production records;
(ii) Production lost due to uninsured causes;
(iii) Unharvested production; and
(iv) Potential production on insured acreage you intend to abandon or no longer care for, if you and we agree on the appraised amount of production. Upon such agreement, the insurance period for that acreage will end. If you do not agree with our appraisal, we may defer the claim only if you agree to continue to care for the crop. We will then make another appraisal when you notify us of further damage or that harvest is general in the area unless you harvested the crop, in which case we will use the harvested production. If you do not continue to care for the crop, our appraisal made prior to deferring the claim will be used to determine the production to count; and
(2) All harvested production from the insurable acreage.
(d) Any prune production harvested for fresh fruit will be converted to a dried prune weight basis by dividing the total amount (in tons) of fresh fruit production by 3.1.
(e) Any production of substandard prunes resulting from damage by insurable causes will be adjusted based on the average size count as indicated on the applicable Dried Fruit Association (DFA) Inspection Report and Certification Form. Any insurable damage will be adjusted by:
(i) Dividing the value per ton of such substandard prunes by the market price per ton for standard prunes (of the same size count); and
(ii) Multiplying the result by the number of tons of such prunes.

12. Written Agreements

Terms of this policy which are specifically designated for the use of written agreements may be altered by written agreement in accordance with the following:
(a) You must apply in writing for each written agreement no later than the sales closing date, except as provided in section 12(e);
(b) The application for a written agreement must contain all variable terms of the contract between you and us that will be in effect if the written agreement is not approved;
(c) If approved, the written agreement will include all variable terms of the contract, including, but not limited to, crop type or varietal group, the guarantee, premium rate, and price election;
(d) Each written agreement will only be valid for one year (If the written agreement is not specifically renewed the following year, insurance coverage for subsequent crop years will be in accordance with the printed policy); and
(e) An application for a written agreement submitted after the sales closing date may be approved if, after a physical inspection of the acreage, it is determined that no loss has occurred and the crop is insurable in accordance with the policy and written agreement provisions.

Signed in Washington, D.C., on July 3, 1997.

Suzette Dittrich,

Deputy Manager, Federal Crop Insurance Corporation.

[FR Doc. 97–18060 Filed 7–9–97; 8:45 am]

BILLING CODE 3410–08–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA No. 166P]

21 CFR Part 1308

Schedules of Controlled Substances: Proposed Placement of Butorphanol into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) to place the substance butorphanol, including its salts and optical isomers, into Schedule IV of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) that butorphanol be added to Schedule IV and on an evaluation of the relevant data by the DEA. If finalized, this action will impose the regulatory controls and criminal sanctions of Schedule IV on

those who handle butorphanol and products containing butorphanol.

DATES: Comments, objections and requests for a hearing must be submitted on or before August 11, 1997.

ADDRESSES: Comments, objections and requests for a hearing should be submitted in quintuplicate to the Acting Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537; Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: Butorphanol, currently a non-controlled substance is classified as an opioid agonist-antagonist analgesic that is marketed as a prescription drug under the trade name Stadol® for the relief of moderate to severe pain in humans. It is also marketed as a veterinary product under the trade names Torbugesic® and Torbutrol® for use in horses and dogs. It was first marketed as an injectable product in 1979. Although there was limited abuse of the injectable product among certain populations, significant abuse was not observed until after the nasal spray was introduced in 1992.

The Acting Deputy Administrator of the DEA received a letter dated September 30, 1996, from the Assistant Secretary for Health, on behalf of the Secretary of the DHHS, recommending that the drug product, Stadol NS Nasal Spray, be placed into Schedule IV of the CSA. Enclosed with the September 30, 1996 letter from the Assistant Secretary was a scientific and medical evaluation prepared by the Food and Drug Administration (FDA). The document contained a review of the factors which the CSA requires the Secretary to consider [21 U.S.C. 811(b)]. Correspondence from the Acting Assistant Secretary for Health dated June 19, 1997, confirmed that the DHHS recommendation included the substance butorphanol and its salts and isomers.

The factors considered by the Assistant Secretary for Health and the DEA with respect to butorphanol were:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effect;

(3) The state of current scientific knowledge regarding the drug;

(4) Its history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) What, if any, risk there is to the public health;

(7) Its psychic or physiological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

The following are summaries of the abuse potential and actual abuse of butorphanol based on the information reviewed by the DEA, including the scientific and medical evaluation of the DHHS.

Summary of Abuse Potential

Butorphanol's profile of effects resembles that of an opioid with either mixed agonist-antagonist actions or partial agonist effects, rather than full mu agonist effects, like morphine. Butorphanol's actions are mediated via three different opioid receptor subtypes: mu, kappa, and delta opioid receptors, showing a 12:1 mu:kappa and 34:1 mu:delta selectivity. Butorphanol's selectivity for mu receptors is consistent with its mu agonist discriminative stimulus, self-administration and antinociceptive profile of effects which are similar to those of morphine, codeine and fentanyl, all Schedule II controlled substances. Butorphanol's selectivity for kappa receptors is consistent with its sedation and respiratory depression which are similar to those of kappa agonists such as pentazocine, a Schedule IV substance under the CSA.

Preclinical and clinical studies show that butorphanol produces reinforcing effects that are less than those of morphine. Butorphanol administered transnasally, intramuscularly, or intravenously in either normal volunteers or former opioid abusers produces positive mood and reinforcing effects in humans (i.e., high, drug-liking). In both opiate-abusing and normal volunteer subjects, butorphanol's subjective effects differ from those of full mu opiate agonists. Compared to an equivalent dose of morphine, butorphanol produces equivalent positive subjective effects, but greater aversive or dysphoric effects, including greater disruption of behavior, sedation, confusion, and difficulty concentrating. Butorphanol administered transnasally or intramuscularly produces similar onsets of effects, rates of elimination, and profiles of effects, however, the magnitudes of effects were greater after intramuscularly administered butorphanol. These studies show that the abuse potential of butorphanol does not differ depending upon the route of administration or preparation, and that the abuse potential of butorphanol is lower than that of morphine and similar to that of pentazocine.

Butorphanol can induce physical and psychological dependence in animals and humans. There is evidence that use of butorphanol produces tolerance and dependence, results in drug-seeking and craving, and its abrupt discontinuation produces an opioid-like withdrawal syndrome. During clinical trials, three percent of the 161 patients who used butorphanol for two months or longer reported behavioral symptoms suggesting possible abuse, and approximately one percent of these patients reported significant overuse. Chronic use of butorphanol results in reports of abuse and self-reported addiction and discontinuation results in a mild withdrawal syndrome. Withdrawal such as anxiety, agitation, and diarrhea are observed. The physical dependence and withdrawal syndrome produced by butorphanol are similar to those observed after long term administration of pentazocine. Consistent with its partial antagonist effects, butorphanol can precipitate withdrawal in animals and humans maintained on mu agonists.

Summary of Actual Abuse and Diversion

For about a decade after butorphanol was first approved for marketing as an injectable product in the United States, reports of abuse were received only occasionally. This was likely due to its limited availability and therapeutic indication. However, following the introduction of the nasal spray product in the United States in 1992, abuse dramatically increased. Many of the abuse reports came from state authorities. At their November 1996 annual meeting, the National Association of State Controlled Substances Authorities (NASCA) recognized that the increasing abuse and diversion of butorphanol warranted its scheduling. Furthermore at this meeting, NASCA passed a resolution urging FDA and DEA to expeditiously place butorphanol into Schedule III of the CSA.

Butorphanol has been a source of increasing incidents of abuse and diversion since 1992. DEA has received reports from 44 states indicating that butorphanol is being abused, diverted and trafficked. These reports have been received from DEA Diversion Investigators, physicians, State Boards of Pharmacies, the National Association of State Controlled Substances Authorities, and State Drug Enforcement officials. They show that butorphanol is stolen from retail and hospital

pharmacies and is diverted through forged and altered prescriptions, improper prescribing and inappropriate dispensing, doctor shopping, and requests for early refills. Additionally, butorphanol abuse is associated with escalating use and drug seeking behavior.

In response to increasing reports of abuse and diversion, six U.S. states and Canada have administratively scheduled butorphanol, and several other states have proposals pending to schedule butorphanol. Some individual hospital pharmacies handle butorphanol as a controlled substance requiring the same recordkeeping, change of shift audits, and security as though the products were already scheduled. In many cases, the initial use of butorphanol is for pain relief, however, escalation of dose and drug seeking of butorphanol have been reported.

In 1994 the FDA, in consultation with the DEA, conducted a survey of State Drug Program Directors, Boards of Pharmacy, and Drug Enforcement officials to provide information on the abuse, trafficking, and diversion of butorphanol. The results of the FDA's survey of the states on the ''Abuse, Misuse, Diversion of Stabol Injectable and Stadol Nasal Spray'' confirm the reports of increasing abuse of butorphanol. State Boards of Pharmacy, State Drug Program Directors, and State Drug Enforcement officials from 46 states and Guam responded to the survey. In November 1995, the FDA issued a final report on this survey. Eighty-three percent of the respondents stated that they were aware of non-medical use, diversion or abuse of butorphonol in their state. Fifteen percent of the states have attempted to regulate butorphanol as a controlled substance, and 44 percent of the states reported that non-regulatory entities, such as hospitals, nursing homes, and clinics have found it necessary to institute special controls beyond those of normal prescription drugs to limit access to the drug. Of the states that responded, 74 percent reported that the nasal spray was abused and 52 percent reported that the injectable was abused. Approximately 60 percent of the states cited that the drug's source was from overprescribing, 55 percent from forged or altered prescriptions and six percent from ''the street''. Twenty-five percent of the states were aware of excessive prescription refill data from health insurance payment plans. Forty-eight percent of the states were aware of thefts of butorphanol and 11 percent of the states reported product tampering. The survey provided information that butorphanol abusers crossed all socioeconomic levels.

Relying on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health, received in accordance with section 201 (b) of the Act (21 U.S.C. 811 (b)), and the independent review of the DEA, the Acting Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

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

(2) Butorphanol has a currently accepted medical use in treatment in the United States; and

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

Based on these findings, the Acting Deputy Administrator of the DEA concludes that butorphanol, including its salts and isomers, warrants control in Schedule IV of the CSA.

Interested persons are invited to submit their comments, objections or requests for a hearing, in writing, with regard to this proposal. Requests for a hearing should state, with particularity, the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the Acting Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537. Attention: DEA Federal Register Representative/CCR. In the event that comments, objections, or requests for a hearing raise one or more issues which the Acting Deputy Administrator finds warrants a hearing, the Acting Deputy Administrator shall other a public hearing by notice in the **Federal Register,** summarizing the issues to be heard and setting the time for the hearing.

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, section 3(d)(1). The Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small-business entities. Butorphanol products are prescription drugs used to treat moderate to severe pain. Handlers of butorphanol also handle other opiate analgesics which are controlled substances and are already subject to the regulatory requirements of the CSA.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

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 competitions, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule, if finalized, will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, drug traffic control, narcotics, prescription drugs.

Under the authority vested in the Attorney General by section 210(a) of the CSA [21 U.S.C. 811(a)], and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Acting Deputy Administrator pursuant to 28 CFR 0.104, the Acting Deputy Administrator hereby proposes that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

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

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

2. Section 1308.14 is proposed to be amended by adding a new paragraph (f)(2) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(f) * * *

(2) Butorphanol (including its optical isomers).

* * * * *

Dated: July 2, 1997.

James S. Milford,

Acting Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 97–17961 Filed 7–9–97; 8:45 am]

BILLING CODE 4410–09–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WI53–03–7301; FRL–5855–9]

Public Hearing and Comment Period on the Proposed Redesignation of the Forest County Potawatomi Community to a PSD Class I area; State of Wisconsin

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Environmental Protection Agency (EPA) under its Prevention of Significant Deterioration (PSD) Program proposed to redesignate a portion of the Forest County Potawatomi (FCP) Community's lands to Class I for PSD purposes on June 29, 1995, (60 FR 33779). EPA is now holding two informational meetings and public hearings on the FCP redesignation request, and is establishing a new close of the public comment period on its proposed approval of the FCP's redesignation request.

DATES: A general informational meeting and public hearing on the redesignation will be held in Carter, Wisconsin, starting at 4:00 pm CDT on August 12, 1997. The second meeting and public hearing will be held in Rhinelander, Wisconsin, starting at 1:00 pm CDT on August 13, 1997.

All written comments on the FCP redesignation must be received by September 15, 1997 to be considered by EPA in making its final decision on the redesignation request.

ADDRESSES: The August 12, 1997 meeting and public hearing will be held at the Indian Springs Lodge on Highway 32 in Carter, Wisconsin, and the August 13, 1997, meeting and public hearing will be held at the Holiday Inn Rhinelander, 668 West Kemp Street, Highway 8 and 47, Rhinelander, Wisconsin.

All written comments on this redesignation request and proposed approval should be addressed to: Carlton Nash, Chief, Regulation Development Section, EPA (AR–18J), 77 West Jackson Boulevard, Chicago, Illinois 60604.

Additional information used in developing the proposal is available during normal business hours for public inspection and copying at the Air Programs Branch, Region 5, EPA (AR–18J), 77 West Jackson Boulevard, Chicago, Illinois 60604. A copy of these documents is also available for inspection at the Crandon Public Library, 104 South Lake Avenue, Crandon, Wisconsin 54520–1458, (715) 478–3784.

FOR FURTHER INFORMATION CONTACT: Constantine Blathras, EPA Region 5 (AR–18J), 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–0671.

SUPPLEMENTARY INFORMATION: The EPA under its PSD Program (Part C of the Clean Air Act) proposed to redesignate a portion of the FCP Community's lands to Class I for PSD purposes in the June 29, 1995, **Federal Register** (60 FR 33779). The intent of the PSD program is to prevent deterioration of existing air quality. The Act provides for three basic classifications, with Class I being the designation which allows the least amount of degradation. States and Indian governing bodies may request reclassification of areas under their jurisdiction to accommodate the social, economic, and environmental needs and desires of the local population.

On February 14, 1995 the FCP Tribal Council submitted to EPA a proposal to redesignate certain FCP Reservation lands from Class II to Class I. These lands are limited to parcels over 80 acres, only in Forest County, and held in trust for the Tribe by the Federal government. EPA evaluated the FCP request in relationship to the requirements of the Act and proposed for public comment to approve it. EPA scheduled in its June 29, 1995 proposal a public hearing and established a public comment period. Based on a request by the Governors of Wisconsin and Michigan to enter into negotiations on the proposed redesignation, EPA subsequently canceled the public hearing and left open the public comment period until further notice (60 FR 40139).

EPA is now scheduling two informational meetings on Class I PSD redesignations in general, each immediately followed by a public hearing on the FCP redesignation request in particular. The first meeting and public hearing will be held at the Indian Springs Lodge on Highway 32 in Carter, Wisconsin, starting at 4:00 pm CDT, on August 12, 1997; and the second meeting and public hearing will be held at the Holiday Inn Rhinelander, 668 West Kemp Street, Highway 8 and 47, Rhinelander Wisconsin, starting at 1:00 pm CDT on August 13, 1997.

EPA is also establishing a new close of the pubic comment period. All written comments on the proposed FCP redesignation must now be received by September 15, 1997 to be considered by EPA in making its final decision on the redesignation request. For additional information on the EPA's proposed approval of the FCP redesignation request, please see EPA's proposal in the June 29, 1995 **Federal Register** and/or the additional material available at both the Region 5 offices and the Crandon Public Library.

Administrative Review

This action has been classified as a Table 3 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225), as revised by an October 4, 1993 memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation. The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for a PSD Class I redesignation. Each request for redesignation shall be considered separately and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. Section 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. sections 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000. The proposed action does not have a significant direct impact on small entities and may only prospectively affect the amount of air quality deterioration that is allowed from major stationary sources and major modifications, as defined by 40 CFR 52.21, and will not result in any significant additional requirements for small entities. Therefore, I certify that this action does not have a significant impact on a substantial number of small entities.