5 U.S.C. 553 or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Sharron Cook, Regulatory Policy Division, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects in 15 CFR Part 744

Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended, as follows:

PART 744—[AMENDED]

1. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of August 15, 1995 (60 FR 42767, August 17, 1995); Notice of August 14, 1996 (61 FR 42527, August 15, 1996); and Notice of August 13, 1997 (62 FR 43629, August 15, 1997).

2. Section 744.1 is amended by revising paragraph (c) to read as follows:

§ 744.1 General provisions.

* * * * *

(c) A list of entities is included in Supplement No. 4 to this part 744 of the EAR (Entity List). Exporters are hereby informed that these entities are ineligible to receive any items subject to the EAR without a license to the extent specified in the supplement. License applications will be reviewed under the license review standards set forth in this part 744. No License Exceptions are available for exports or reexports to listed entities of specified items.

3. Supplement No. 4 to part 744 is amended by removing the entity ''Bharat Electronics LTD'' and adding in its place the following entity to read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Bharat Electronics Limited (BEL) in Bangalore, India; and Bharat Electronics Limited (BEL) in Hyderabad, India; for all items subject to the EAR having a classification other than EAR99. In addition, exporters are reminded to follow ''BXA's Know Your Customer Guidance and Red Flags'', see Supplement No. 3 to part 732 of the EAR, with regard to the specific end-use of any item subject to the EAR destined to any Bharat Electronics Limited located in India.

* * * * *

Dated: September 26, 1997.

James A. Lewis,

Acting Assistant Secretary for Export Administration.

[FR Doc. 97–26048 Filed 9–30–97; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA–166F]

Schedules of Controlled Substances Placement of Butorphanol Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance butorphanol, including its salts and optical isomers, into Schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, dispensing, importation and exportation of butorphanol and products containing butorphanol.

EFFECTIVE DATE: October 31, 1997.

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 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 Department of Health and Human Services (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 Acting Deputy Administrator of the DEA, in a July 10, 1997, **Federal Register** notice (62 FR 37004 proposed to place butorphanol into Schedule IV of the CSA. The notice provided an opportunity for all interested persons to submit their comments, objections, or requests for a hearing in writing on the proposed scheduling of butorphanol until August 11, 1997. DEA received nine comments regarding the proposal. Comments in support of the proposal were received from six organizations: National Association of Boards of Pharmacy, Missouri Department of Mental Health, Missouri Department of Health, Missouri Department of Economic Development's State Board of Registration for the Healing Arts, Texas State Board of Pharmacy and Public Citizen. The American Veterinary Medical Association noted that controlled substances are subject to additional recordkeeping and storage requirements, but recognized the abuse potential of butorphanol. It recommended that if butorphanol is to be controlled, it be classified at a level no greater than Schedule IV.

Bristol-Myers Squibb commented that the abuse potential of butorphanol nasal spray is low, as evidenced by the low number of adverse reaction reports received by the company per number of prescriptions. Bristol-Myers Squibb did support the placement of butorphanol in Schedule IV. Fort Dodge Animal Health commented that there was little abuse of the butorphanol veterinary products and did not support the scheduling of the veterinary products. This scheduling action, however, is based on the abuse and dependence potentials of the substance butorphanol. It was determined that butorphanol, whether administered orally, intravenously, or intranasally, had an abuse potential consistent with control in Schedule IV of the CSA. Furthermore, available data does not differentiate the abuse potential of butorphanol-containing

human products from that of veterinary products. Fort Dodge presented no additional data in this regard.

Based 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) 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 in the CSA. The Schedule IV controls of butorphanol will be effective on October 31, 1997, except as indicated below. In the event that the regulations impose special hardships on the registrants, the DEA will entertain any justified request for an extension of time to comply with the Schedule IV regulations regarding butorphanol. The applicable regulations are as follows:

1. Registration. Any person who manufactures, distributes, dispenses, imports or exports butorphanol activities or who engages in research or conducts instructional activities with butorphanol, or who proposes to engage in such activities, must submit an application for Schedule IV registration in accordance with Part 1301 of Title 21 of the Code of Federal Regulations. Any person who is currently lawfully engaged in any of the above activities must submit an application for registration by October 31, 1997. Any such person may then continue their lawful activities until the Administration has approved or denied that application.

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

3. Labeling and Packaging. All labels on commercial containers of, and all labeling of, butorphanol which is distributed on and after April 1, 1998 shall comply with the requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations. Any commercial containers of butorphanol packaged on or before April 1, 1998 and not meeting the requirements specified in §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations shall not be distributed on or after July 1, 1998.

4. Inventory. Registrants possessing butorphanol are required to take inventories pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations.

5. Records. All registrants must keep records pursuant to §§ 1304.03, 1304.04 and 1304.21–1304.23 of Title 21 of the Code of Federal Regulations.

6. Prescriptions. All prescriptions for butorphanol are to be issued pursuant to §§ 1306.03–1306.06 and 1306.21–1306.26 of Title 21 of the Code of Federal Regulations. All prescriptions for products containing butorphanol issued on or before October 31, 1997, if authorized for refilling, shall as of that date be limited to five refills and shall not be refilled after April 1, 1998.

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

8. Criminal Liability. Any activity with butorphanol not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful on or after October 31, 1997.

In accordance with the provisions of 21 U.S.C. 811(a) of the CSA, 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 products. Handlers of butorphanol also handle other controlled substances which 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 § 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 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 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 201(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 amends 21 CFR part 1308 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 amended by adding a new paragraph (f)(2) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(f) * * *

(2) Butorphanol (including its optical isomers)—9720

Dated: September 22, 1997.

James S. Milford,

Acting Deputy Administration.

[FR Doc. 97–25969 Filed 9–30–97; 8:45 am]

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