

Rules and Regulations

Federal Register

Vol. 62, No. 190

Wednesday, October 1, 1997

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

FARM CREDIT ADMINISTRATION

12 CFR Part 650

RIN 3052-AB72

Federal Agricultural Mortgage Corporation; Receivers and Conservators; Effective Date

AGENCY: Farm Credit Administration.

ACTION: Notice of effective date.

SUMMARY: The Farm Credit Administration (FCA) published a final rule under part 650 on August 15, 1997 (62 FR 43633). The final rule amends the regulations that apply to the Federal Agricultural Mortgage Corporation by adding a subpart to govern a receivership or conservatorship. The final rule implements the receivership/conservatorship authorities granted to the FCA by the Farm Credit System Reform Act of 1996, Pub. L. 104-105 (Feb. 10, 1996) and by previous law. In accordance with 12 U.S.C. 2252, the effective date of the final rule is 30 days from the date of publication in the **Federal Register** during which either or both Houses of Congress are in session. Based on the records of the sessions of Congress, the effective date of the regulations is October 1, 1997.

EFFECTIVE DATE: The regulation amending 12 CFR part 650 published on August 15, 1997 (62 FR 43633) is effective October 1, 1997.

FOR FURTHER INFORMATION CONTACT: Larry W. Edwards, Director, Office of Secondary Market Oversight, Farm Credit Administration, McLean, VA 22102-5090, (703) 883-4051, TDD (703) 883-4444.

(12 U.S.C. 2252(a) (9) and (10))

Dated: September 26, 1997.

Floyd Fithian,

Secretary, Farm Credit Administration Board.

[FR Doc. 97-25978 Filed 9-30-97; 8:45 am]

BILLING CODE 6705-01-P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Part 744

[Docket No. 970428099-7227-04]

RIN 0694-AB60

Revision to Entity List: Bharat Electronics, Ltd. (aka Baharat Electronics, Ltd.), India

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Export Administration Regulations (EAR) provide that the Bureau of Export Administration (BXA) may inform exporters, individually or through amendment to the EAR, that a license is required for exports or reexports to certain entities. The EAR contains a list of such entities. This rule amends the Entity List by revising the entry "Bharat Electronics LTD, (aka Baharat Electronics, Ltd.) located in India, for all items subject to the EAR". The entry will now read, "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 specific end-use of any item subject to the EAR destined to any Bharat Electronics Limited located in India.

EFFECTIVE DATE: October 1, 1997.

FOR FURTHER INFORMATION CONTACT: Eileen M. Albanese, Office of Exporter Services, Bureau of Export Administration, Telephone: (202) 482-0436.

SUPPLEMENTARY INFORMATION:

Background

General Prohibition Five (§ 736.2(b)(5) of the EAR) prohibits exports to certain end-users or end-uses, as described in Part 744, without a license. In the form of Supplement No. 4 to part 744, BXA maintains an "Entity List" to provide notice informing the public of certain entities subject to such licensing requirements.

This rule narrows the scope of products subject to the end-user license

requirement and clarifies the end-user by specifying the facilities of Bharat Electronics by city name. Other Bharat Electronics Limited entities would be subject to normal licensing procedures, with the caveat that you may not, without a license, knowingly export or reexport any item subject to the EAR to an end-user or end-use that is prohibited by part 744 of the EAR, per general prohibition five.

Although the Export Administration Act (EAA) expired on August 20, 1994, the President invoked the International Emergency Economic Powers Act and continued in effect, to the extent permitted by law, the provisions of the EAA and the EAR in Executive Order 12924 of August 19, 1994, notice of August 15, 1995 (60 FR 42767), and August 14, 1996 (61 FR 42527); and August 13, 1997 (62 FR 43629).

Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. This rule involves a collection of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control number 0694-0088.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (Sec. 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under

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