proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1308]

NALBUPHINE

Controlled Substances

Nalbuphine is a controlled substance in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. § 812(c) Schedule II (a)(1); § 1308.12(b)(1), Title 21 of the Code of Federal Regulations (CFR)).

On January 29, 1973, Endo Laboratories, Inc., Garden City, New York, requested that the Bureau of Narcotics and Dangerous Drugs (BNDD) exclude nalbuphine from all schedules of the Act, and submitted data in furtherance thereof. The Drug Enforcement Administration reviewed this data and by letter dated September 27, 1973, advised Endo that it was withholding initiating proceedings to decontrol nalpuphine until the Food and Drug Administration approved the drug for marketing by granting approval of its New Drug Application (NDA). By copy of the above letter, the Food and Drug Administration was requested to offer its control recommendations on nalbuphine in advance of its granting the NDA.

By letter dated January 23, 1976, the Assistant Secretary for Health, Department of Health, Education, and Welfare (HEW), recommended to the Drug Enforcement Administration that nalbuphine be removed from controls of the Act. Enclosed with the letter were the HEW scientific and medical evaluations of nalbuphine.

The Assistant Secretary's recommendation was based upon HEW's analysis of data submitted by it by the sponsor for obtaining an approved NDA for nalbuphine, and because the magnitude of abuse potential of nalbuphine does not seem to HEW to presently justify control.

In his letter, the Assistant Secretary stated that future control considerations of nalbuphine would be undertaken if the Food and Drug Administration's continuing analysis of relevant data on the drug indicated a need for such action.

Based upon the investigations of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to Section 201(b) of the Act (21 U.S.C. 811(b)), the Administrator of the Drug Enforcement Administration finds that nalbuphine does not have sufficient potential for abuse or abuse liability to justify its continued control in any schedule under the Act.

Therefore, under the authority vested in the Attorney General by Section 201 (a) of the 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 Part O), the Administrator hereby proposes that 21 CFR § 1308.12 (b)(1) be amended as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding naloxone, naltrexone, apomorphine, and nalbuphine, and their respective salts, but including the following:

(1) Raw opium	9600
(2) Opium extracts	9610
(3) Opium fluid extracts	9620
(4) Powdered opium	9639
(5) Granulated opium	9640
(6) Tincture of opium	9630
(7) Codeine	9050
(8) Ethylmorphine	9190
(9) Etorphine hydrochloride	9059
(10) Hydrocodone	9193
(11) Hydromorphone	9150
(12) Metopon	9260
(13) Morphine	9300
(14) Oxycodone	9143
(15) Oxymorphone	9652
(16) Thebaine	9333

* * * * *

All interested persons are invited to submit their comments or objections in writing regarding this proposal. These comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, United States Department of Justice, 1405 Eye Street, NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative, and must be received on or before June 14, 1976. In the event that an interested party submits objections to this proposal which present reasonable grounds for this rule not to be finalized and requests a hearing in accordance with 21 CFR 1308.45, the party will be notified by registered mail of the time and place that the hearing will be held. If objections submitted do not present such reasonable grounds, the party will be so advised by registered mail.

If no objections presenting grounds for a hearing on the proposal are received within the time limitations, or all interested parties waive or are deemed to waive their opportunity for a hearing or to participate in a hearing, the Administrator, after giving considerations to written comments and objections, will issue his final order pursuant to 21 CFR 1308.45 without a hearing.

Dated: April 28, 1976.

PETER B. BENSINGER,
Administrator, Drug Enforcement Administration.

[FR Doc.76-13694 Filed 5-10-76;8:45 am]

DEPARTMENT OF COMMERCE

National Bureau of Standards

[15 CFR Part 10]

STRUCTURAL GLUED LAMINATED TIMBER STANDARD

Proposed Amendment

Notice is hereby given of a proposed amendment to Voluntary Product Standard PS 56-73, "Structural Glued Laminated Timber," developed under the Department's "Procedures for the Development of Voluntary Product Standards" (15 CFR Part 10, as amended; 35 FR 8349 dated May 28, 1970).

The proposed amendment provides clarification in line with changing technology and marketing practices, updates referenced publications, and adds definitions. The amendment will have no anticompetitive effects and can be reasonably injected into PS 56-73 without disturbing the general applicability of the standard. The changes are not comprehensive in nature, have no substantive effect on the standard, and in no way alter the level of performance or safety of the product.

Copies of PS 56-73, the proposed amendment, or both may be obtained from the Standards Development Services Section, National Bureau of Standards, Washington, D.C. 20234.

Any comments or objections concerning the proposed amendment should be made in writing to the Standards Development Services Section on or before June 25, 1976.

Dated: May 4, 1976.

ERNEST AMBLER,
Acting Director.

[FR Doc.76-13567 Filed 5-10-76;8:45 am]

CIVIL AERONAUTICS BOARD

[14 CFR Parts 207, 208, 296]

[EDR-297; Docket 28256; Dated May 5, 1976]

CHARTERING BY COOPERATIVE SHIPPERS ASSOCIATIONS AND JOINT LOADING BETWEEN COOPERATIVE SHIPPERS ASSOCIATIONS AND AIR FREIGHT FORWARDERS

Notice of Proposed Rulemaking

MAY 5, 1976.

Notice is hereby given that the Civil Aeronautics Board is considering the