DEPARTMENT OF JUSTICE

Drug Enforcement Administration

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, 1976, Endo Laboratories, Inc., Garden City, New York, requested that the Bureau of Narcotics and Dangerous Drugs (BNDD) of the National Drug Enforcement Administration review data in furtherance thereof. The Drug Enforcement Administration reviewed the data and on February 22, 1976, advised Endo that it was withholding initiating proceedings to decontrol nalbuphine 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 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. To 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, including naloxone, nalbuphine, apomorphine, and nalbuphine, and their respective salts, but excluding the following:

(1) Raw opium
(2) Opium extract
(3) Opium fluid extract
(4) Powdered opium
(5) Granulated opium
(6) Tincture of opium
(7) Codeine
(8) Ethylmorphine
(9) Ethorphine hydrochloride
(10) Hydromorphone
(11) Hydromorphone hydrochloride
(12) Metopon
(13) Morphine
(14) Oxycodone
(15) Oxyphorphine
(16) Thebaine

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, N.W., 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 of the hearing. If objections submitted do not present such reasonable grounds, the party will be so advised by registered mail.

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.


PETER B. ENZINGER, Administrator, Drug Enforcement Administration.

[FR Doc. 76-13568 Filed 5-30-76; 8:45 am]

DEPARTMENT OF COMMERCE

National Bureau of Standards

[15 CFR Part 10]

STRUCTURAL GLUED LAMINATED TIMBER STANDARD

Proposed Amendment


The proposed amendment provides 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.


ERNST AMBLER, Acting Director.

[CFR Doc. 76-13567 Filed 5-30-76; 8:45 am]

CIVIL AERONAUTICS BOARD

[14 CFR Parts 207, 208, 296]

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

Notice of Proposed Rulemaking


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