

**[DDB BOARD REGULATION NO. 2, s. 1993, May
20, 1993]**

**CLASSIFYING PRECOMPOUNDED UNIT DOSE FORMULATIONS OF
NALBUPHINE AND ITS SALTS, ISOMERS, AND SALTS OF
ISOMERS AS EXEMPT PROHIBITED DRUGS**

WHEREAS, precompounded unit dose formations of Nalbuphine and its salts, isomers and salts of isomers have been found being so abused as to cause a public health and social problem;

WHEREAS, there is an urgent need for preventive measures against escalation of the abuse incidence wherein these formulations are involved and for the suppression of the illicit drug supply;

WHEREAS, these formulations have therapeutic value and have to be available for their specific indications;

WHEREAS, these formulations are presently not listed in any of the Schedules under the 1961 Single Convention on Narcotic Drugs, as amended;

NOW, THEREFORE, the Dangerous Drugs Board, pursuant to its powers under Section 36 (a) of R.A. 6425, as amended, and in accordance with its decision arrived at in its meeting of _____ 1993, hereby prescribes the following:

SECTION 1. Definitions — As used in this Regulation, the terms:

1.1 Precompounded Unit Dose Formulation refers to the product which has been compounded in advance by the pharmaceutical company in accordance with Current Good Manufacturing Practice (CGMP) and does not require further manipulation by the prescribing practitioner.

1.2 Nalbuphine refers to:

INTERNATIONAL NON- PROPRIETARY NAME (INN)	CHEMICAL NAME	BRAND NAME
Nalbuphine	17-Cyclobutylmethyl-7,8- dihydro-14 hydroxy-17-normorphine (-)-(5R,6S,14S)-9a-Cyclo- butylmethyl-4,5-epoxymor-phinan- 3,6,14-triol	Nubain

1.3 Salts, Isomers, Salts of Isomers refers to Nalbuphine salts, isomers, and salts