BOARD REGULATION No. 1
Series of 2010

SUBJECT: INCLUSION OF NALBUPHINE HYDROCHLORIDE IN THE LIST OF DANGEROUS DRUGS

WHEREAS, pursuant to Section 93, Article XI of Republic Act No. 9165, otherwise known as the “Comprehensive Dangerous Drugs Act of 2002”, the Board is given the power to reclassify, add to or remove any drug or substance from the list of dangerous drugs;

WHEREAS, among the drugs that are available in the market, Nalbuphine Hydrochloride is widely used to cure moderate to severe pain, but has been found to have serious side effects necessitating its administration only by a trained medical practitioner with a valid S-2 license;

WHEREAS, studies made also show that Nalbuphine Hydrochloride, when used or administered indiscriminately, has the capacity to produce dependence and is found to be the 5th most commonly encountered drug of abuse by victims seeking treatment and rehabilitation in various rehabilitation centers according to DDB 2009 admission reports;

WHEREAS, there have also been numerous reports of abuse of Nalbuphine Hydrochloride in many major cities in the country;

WHEREAS, the abuse of Nalbuphine Hydrochloride, an injectable drug, and the attendant practice of needle sharing, constitute a serious public health and social problem, like the occurrence and spread of HIV-AIDS, malaria, and hepatitis;

WHEREAS, because of the danger posed by the abuse of Nalbuphine Hydrochloride, there is a need to include Nalbuphine Hydrochloride in the list of dangerous drugs.

NOW, THEREFORE, pursuant to Section 93, Article XI of Republic Act 9165, otherwise known as the “Comprehensive Dangerous Drugs Act of 2002”, on the initiative of the Philippine Drug Enforcement Agency (PDEA) and the Department of Health (DOH), and after a series of public hearings conducted by the Board on 10 February 2006, 28 March 2007 and 06 May 2009, the Board, finding merit in the inclusion of Nalbuphine Hydrochloride in the list of dangerous drugs and after considering the factors therein provided, hereby promulgates the following:

SECTION 1. Inclusion of Nalbuphine Hydrochloride, and the salts, isomers, and complexes of Nalbuphine and their preparations, in the list of dangerous drugs.

SECTION 2. Nalbuphine Hydrochloride, and the others mentioned in Section 1 hereof as applicable, shall be prescribed only by a medical practitioner with a valid S-2 license through a special prescription form issued by and obtainable from the Department of Health, which shall cover a maximum of forty (40) mg. of Nalbuphine Hydrochloride in every prescription.
SECTION 3. Nalbuphine Hydrochloride, and the others mentioned in Section 1 hereof, shall be subject to the provisions of RA 9165 and Board Regulation No. 3, Series of 2003 and other applicable issuances of the Board.

SECTION 4. This Regulation shall take effect fifteen (15) days after its publication in two (2) newspapers of general circulation and after its registration with the Office of the National Administrative Register (ONAR), U.P. Law Center, Diliman, Quezon City.

APPROVED and ADOPTED, this 16th day of December, in the year of Our Lord, 2010 in Quezon City.

(Sgd) Secretary ANTONIO A. VILLAR, JR.
Chairman, Dangerous Drugs Board

Attested by:

(Sgd) Undersecretary EDGAR C. GALVANTE
Secretary of the Board