STATUS DECISION OF CONTROLLED
AND NON-CONTROLLED SUBSTANCE(S)

Substance: Nalbuphine-6-glucuronide, Nalbuphine-3-glucuronide, Nalbuphine-3-sulfate

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

Controlled ☑
Not Controlled □

under the schedules of the *Controlled Drugs and Substances Act* (CDSA) for the following reason(s):

- The substances are derivatives of nalbuphine and are not excluded from item 10 of Schedule I to the CDSA.

Prepared by: ___________________________ Date: Sept 16th 2010
Evelyn Soo

Verified by: ___________________________ Date: __________
Marianne Tang

Approved by: ___________________________ Date: __________
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Nacer Silarbi
Drug Status Report

Drug:
I - Nalbuphine-6-glucuronide
II - Nalbuphine-3-glucuronide
III - Nalbuphine-3-sulfate

Drug Name Status:
I - Nalbuphine-6-glucuronide
II - Nalbuphine-3-glucuronide
III - Nalbuphine-3-sulfate are common names.

Chemical Name:
I - 17-(Cyclobutylmethyl)-4,5alpha-epoxymorphinan-3,14-diol-6-beta-D-glucopyranuronic acid
II - 17-(Cyclobutylmethyl)-4,5alpha-epoxymorphinan-6,14-diol-3-beta-D-Glucopyranuronic acid
III - 17-(Cyclobutylmethyl)-4,5alpha-epoxymorphinan-6,14-diol-3-sulfate

Chemical structure:

![Chemical Structure Diagrams]

I
II
III
Nalbuphine
Molecular Formula: I - C_{27}H_{15}NO_{10}; II - C_{27}H_{15}NO_{10}; III - C_{21}H_{27}NO_{7}S

Pharmacological class / Application: Pharmaceutical-related substances

CAS-RN: NONE

International status:

US: The substance is not listed specifically in the Controlled Substances Act and is not mentioned anywhere on the DEA website.

United Nations: The substance is not listed on the Yellow List - List of Narcotic Drugs under International Control nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Nalbuphine-6-glucuronide, nalbuphine-3-glucuronide and nalbuphine-3-sulfate are metabolites of nalbuphine. While nalbuphine is explicitly excluded from the heading “Morphinans, their salts, derivatives and salts of derivatives” as sub-item 15 of item 10 of Schedule I to the CDSA, these substances are morphinans and are not considered to fall under the “but not including” heading of item 10 of Schedule I. A review of other related substances of nalbuphine including for example bis-nalbuphine and N-(cuclomethyl)noroxymorphone also determined them to be controlled under item 10 of Schedule I to the CDSA.

Recommendation: Nalbuphine-6-glucuronide, nalbuphine-3-glucuronide and nalbuphine-3-sulfate are included under item 10 of Schedule I to the CDSA and are controlled substances.

Date: 16 September 2010