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

Substance: Nalfurafine

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 substance contains the core structure of the morphinans and therefore included under item 10 of Schedule I to the CDSA.

Prepared by: ___________________________ Date: __________

Evelyn Soo

Verified by: ___________________________ Date: __________

Mark Kozlowski

Approved by: ___________________________ Date: __________

DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Brigitte Mainville, OCS
Drug Status Report

**Drug:** Nalfurafine

**Drug Name Status:** Nalfurafine is the proper (INN) name.

**Chemical Name:** (E)-N-(17-(Cyclopropylmethyl)-4,5alpha-epoxy-3,14-dihydroxymorphinan-6beta-yl)-3-(furan-3-yl)-N-methylprop-2-enamide

**Chemical structure:**

![Chemical structure diagram]

**Molecular Formula:** $C_{28}H_{32}N_{2}O_{5}$

**CAS-RN:** 152657-84-6

**Pharmacological class / Application:** k-Opioid Receptor Antagonist

**International status:**

US: Nalfurafine is not listed on the schedules to the US 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, the Green List - List of Psychotropic Substances under International Control, nor the Red List - List of Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances Under International Control.

Canadian Status: Nalfurafine has been reported in the scientific literature to reduce antihistamine sensitive and resistance pruritus in the mouse, and a potentially useful for the management of
pruritus'. Nalfurafine is not currently listed in the schedules to the CDSA. However, the substance contains the core structure of the morphinans, which are currently controlled as item 10 in Schedule I to the CDSA under the heading “Morphinans, their salts, derivatives and salts of derivatives including:”. Therefore, nalfurafine is considered is captured under item 10 of Schedule I to the CDSA.

**Recommendation:** Nalfurafine is included under Item 10 of Schedule I to the CDSA and is a controlled substance.

**Date:** Sept 1st, 2011

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