



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

Substance: Buprenorphine derivatives

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

Controlled [checked]
Not Controlled [unchecked]

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

- The substances are derivatives of buprenorphine and included under item 10(1) of Schedule I to the CDSA.

Prepared by: Evelyn Soo Date: Nov 17th 2010

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

This status was requested by: third party information removed as per agreement with applicant

Drug Status Report

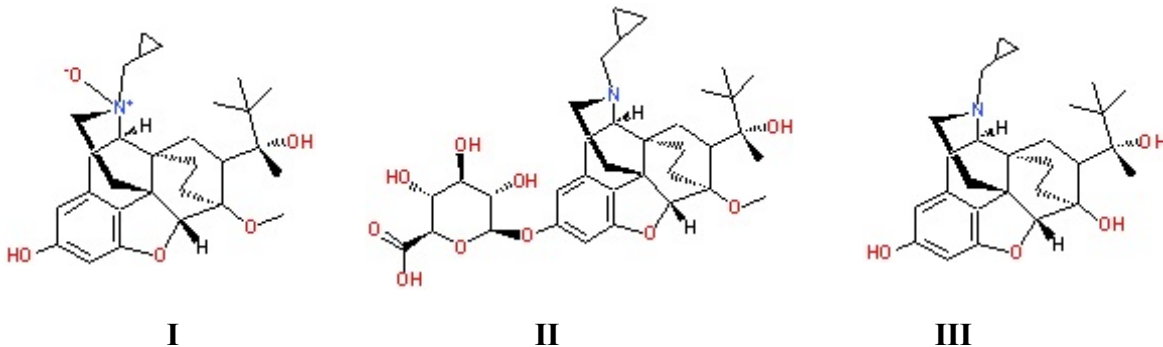
Drug: I - Buprenorphine N-oxide
II - Buprenorphine β -D-glucuronide
III - 6-O-Desmethyl buprenorphine

Drug Name Status: I - Buprenorphine N-oxide
II - Buprenorphine-3-O-glucuronoide
III - 6-O-Desmethyl buprenorphine are the common names.

Chemical Name:

I - (5 α ,7 α (S)-17-(cyclopropylmethyl)- α -(1,1-dimethylethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy- α -methyl-6,14-ethenomorphinan-7-methanol 17-oxide
II - (5 α ,7 α (S))-17-(cyclopropylmethyl)-4,5-epoxy-18,19-dihydro-7-(1-hydroxy-1,2,2-trimethylpropyl)-6-methoxy-6,14-ethenomorphinan-3-yl-beta-D-glucopyranosiduronic acid
III - (5 α ,7 α (S)-17-(cyclopropylmethyl)-4,5-epoxy-18,19-dihydro-7-(1-hydroxy-1,2,2-trimethylpropyl)-6,14-endoethanomorphinan-3,6-diol

Chemical structure:



Molecular Formula: I- $C_{29}H_{41}NO_5$; II - $C_{35}H_{49}NO_{10}$; III - $C_{28}H_{39}NO_4$

Pharmacological class / Application: Pharmaceutical-related substances

CAS-RN: I - 112242-17-8; II - 101224-22-0; III - 130668-48-3

International status:

US: The above-named substances are not currently listed in the schedules to the US Controlled Substances Act.

United Nations: The substances are 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: Buprenorphine N-oxide, buprenorphine β -D-glucuronide and 6-O-desmethyl buprenorphine are morphinans and more specifically, derivatives of buprenorphine. The substances are not currently listed in the CDSA but buprenorphine is listed as item 10(1) in Schedule I to the CDSA under the heading "Morphinans, their salts, derivatives and salts of derivatives including:". Therefore as derivatives of buprenorphine, these substances are captured under buprenorphine and included under item 10(1) of Schedule I to the CDSA.

Recommendation: Buprenorphine N-oxide, buprenorphine β -D-glucuronide and 6-O-desmethyl buprenorphine are included under item 10(1) of Schedule I to the CDSA and are controlled substances.

Date: 17th November 2010