



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

Substance: Naltrexone related substance A

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

Controlled	<input checked="" type="checkbox"/>
Not Controlled	<input type="checkbox"/>

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

- Naltrexone is considered to be "captured" under the heading for item 1 of Schedule I: Opium poppy (*Papaver somniferum*), its preparations, derivatives, alkaloids and salts, including. It has been excluded from item 1 by the "but not including" part of this item.

Structurally related substances such as the following which are listed on the OCS Controlled List are still be included in item 1: Bis-naltrexone; 10-ketonaltrexone; and 10-hydroxynaltrexone.

Salts of substances listed under the "but not including" provision are also excluded from item 1. For example, nalmefene and naloxone are structurally capable of forming salts and both are marketed in Canada as hydrochloride salts. As there is no specific mention of salts in the "but not including" section, a decision has been made that the salts of substances listed under the "but not including" part of item 1 are also excluded from item 1.

As naltrexone related substance A is not excluded from item 1 of Schedule 1, it is included.

Supporting document(s) attached: **X** (Drug Status Report by Mr. M LeBelle)

Prepared by: _____ Date: May 16, 2006
Xiao-Peng Feng

Drug Status Report by: MICHAEL LEBELLE Date: May 16, 2006

Approved by: _____ Date: _____
DIRECTOR, OFFICE OF
CONTROLLED SUBSTANCES

Drug Status Report

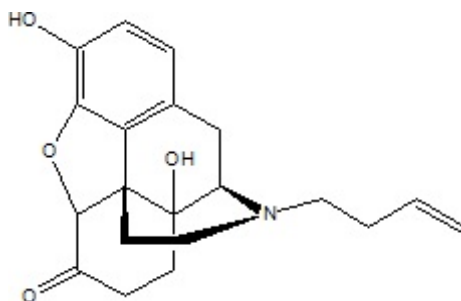
Drug: Naltrexone related substance A

Drug Name Status: Naltrexone related substance A is the common (regulatory - USP) name.

Chemical Name: (5a)-17-(3-Butenyl)-4,5-epoxy-3,14-dihydroxymorphinan-6-one

Other Names: N-(3-Butenyl)-noroxymorphone hydrochloride; N-(3-butenyl)-14-hydroxydihydromorphinone

Chemical structure:



Molecular Formula: $C_{20}H_{23}NO_4$

Pharmacological/chemical class / Application: Drug related substance
International status:

US: The chemical is not currently listed on the US Controlled Substances Act and is not mentioned on the DEA website. However the definition of narcotic drug in the CSA “(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation” may include naltrexone related substances.

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: Naltrexone is considered to be "captured" under the heading for item 1 of Schedule I: Opium poppy (*Papaver somniferum*), its preparations, derivatives, alkaloids and salts, including. It has been excluded from item 1 by the “but not including” part of this item.

Structurally related substances such as the following which are listed on the OCS Controlled List are still be included in item 1: Bis-naltrexone; 10-ketonaltrexone; and 10-hydroxynaltrexone.

Salts of substances listed under the "but not including" provision are also excluded from item 1. For example, nalmefene and naloxone are structurally capable of forming salts and both are marketed in Canada as hydrochloride salts. As there is no specific mention of salts in the "but not including" section, a decision has been made that the salts of substances listed under the "but not including" part of item 1 are also excluded from item 1.

As naltrexone related substance A is not excluded from item 1 of Schedule 1, it is included.

Recommendation: Naltrexone related substance A is included in item 1 of Schedule I to the CDSA and is a controlled substance.