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

Substance:  Hydrocodonediol

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

Controlled  X
Not Controlled  □

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

• Item 1 of Schedule I to the CDSA is “Opium Poppy (Papaver somniferum), its
  preparations, derivatives, alkaloids and salts ... and the salts, derivatives and salts of
derivatives of the substances set out in subitems (1) to (4)”. There then follows a list of
27 substances to illustrate the types of substances included in the item of the schedule.
• Item 1 of Schedule I has been interpreted to include a broad range of substances related
to the opium alkaloids and the substances included specifically in item 1.
• In assessing the status of substances in the past four years, no substance similar to any
  of the opium related substances has been determined to be “non-controlled”, i.e.,
outside the application of the CDSA. During the same period, nine substances related
to the opium alkaloids have been declared to be “controlled”. One of these,
hydrocodone related substance A, was declared to be controlled as it is a derivative of
codine.
• Due to the similarity of the structures of hydrocodonediol and hydrocodone related
  substance A, the former should be considered to be included in item 1 of Schedule I to
the CDSA.

Supporting document(s) attached: X

Prepared by: _______________________________  Date:  2005-06-27
  TIANA BRANCH

Verified by:  _____See email_________________________  Date:  2005-06-24
  MICHAEL LEBELLE

Approved by: _______________________________  Date:  ____________
  DIRECTOR, OFFICE OF

Cdsa\HC\StatusDecisions\A-2013-00235 - Full Disclosure\C-Hydrocodonediol
2005-06-29.wpd
Drug Status Report

**Drug:** Hydrocodonediol

**Drug Name Status:** Hydrocodonediol is the trivial name

**Chemical Name:** 4,6-dihydroxy-3-methoxy-5-oxo-17-methylmorphinan

**Chemical structure:**

![Chemical Structure Image]

**Molecular Formula:** $C_{18}H_{23}NO_4$

**Pharmacological class / Application:** unknown

**International status:**

US: The Controlled Substances Act is broad in its specification of opiates: The term "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.” The “capable of conversion” could be interpreted to include hundreds of chemical substances. It is likely that the subject substance would be considered to be included in the CSA; confirmation of the status of the substance in the US would need to be obtained from the DEA.

United Nations: The drug is not listed on the Yellow List - List of Narcotic Drugs under International Control. The drug is not listed on the Green List - List of Psychotropic Substances under International Control. The drug is not likely considered to be covered by the 1971 Convention as the list of substances included is extended beyond those specifically listed by only specific related substances, for example, ethers, esters, etc. The title substance does fall into this extension.

Canadian Status: Item 1 of Schedule I to the CDSA is “Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including:

(1) Opium

(2) Codeine (methylmorphine)
(3) Morphine (7,8-didehydro--4,5--epoxy--17--methylmorphinan--3,6--diol)
(4) Thebaine (paramorphine)
and the salts, derivatives and salts of derivatives of the substances set out in
subitems (1) to (4), including:"

There then follows a list of 27 substances to illustrate the types of substances
included in the item of the schedule. This list has been interpreted to include, as
well, the salts, derivatives and salts of derivatives of the substances.

Item 1 of Schedule I has been interpreted to include a broad range of substances
related to the opium alkaloids and the substances included specifically in item 1.
In assessing the status of substances in the past four years, no substance similar to
any of the opium related substances has been determined to be “non-controlled”,
i.e., outside the application of the CDSA. During the same period, nine
substances related to the opium alkaloids have been declared to be “controlled”.
One of these, hydrocodone related substance A, was declared to be controlled as
it is a derivative of codeine.

Codeine has the following structure.

![Codeine Structure]

Hydrocodone related substance A has
the following structure.

![Hydrocodone Related Substance A Structure]

For reference the structure of hydrocodone is shown on the next page.
Due to the similarity of the structures of hydrocodonediol and hydrocodone related substance A, the former should be considered to be included in item 1 of Schedule I to the CDSA.

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

June 24, 2005