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

Substance: Drotaverine

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 is considered an analogue of papaverine but does not fall under the heading 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: "third party information removed as per agreement with applicant"
Drug Status Report

Drug: Drotaverine

Drug Name Status: Drotaverine the proper (INN) name.

Chemical Name: 1-(3,4-Diethoxybenzylidene)-6,7-diethoxy-1,2,3,4-tetrahydroisoquinoline

Other Names: 1-Benzyl-3',4',6,7-tetraethoxy-1,2,3,4-tetrahydroisoquinoline

Chemical structure:

Molecular Formula: $C_{24}H_{31}NO_4$

CAS-RN: 14009-24-6 (985-12-6 for HCl)

Pharmacological class / Application: Antispasmodic

International status:

US: Drotaverine 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: Drotaverine is not listed in the schedules to the CDSA. The substance is considered to be an analogue of papaverine and is used as an antispasmodic drug. Papaverine is specifically excluded under the “but not including” provision and is listed as sub-item 1(35) in Schedule I to the CDSA. Since analogues are not included in the heading “Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including:” of item 1 of Schedule I to the CDSA, drotaverine cannot be included under Schedule I to the CDSA.

---

**Recommendation:** Drotaverine is not included in the Schedules to the CDSA and is not a controlled substance.

**Date:** August 31st, 2011