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

Substance: Ganaxolone

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 not an anabolic steroid nor a derivative of an anabolic steroid and therefore cannot be included under item 23 of Schedule IV to the CDSA.

Prepared by: ___________________________ Date: January 24th, 2012

Evelyn Soo

Verified by: ___________________________ Date: __________

Mark Kozlowski

Approved by: ___________________________ Date: __________

DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Tanya Arcand, OCS
Drug Status Report

**Drug:** Ganaxolone

**Drug Name Status:** Ganaxolone is the common name.

**Chemical Name:** Pregnan-20-one, 3-hydroxy-3-methyl-, (3alpha,5alpha)-

**Other Names:** (3alpha,5alpha)-3-Hydroxy-3-methylpregnan-20-one; 3alpha-Hydroxy-3-methyl-5alpha-pregnan-20-one; 3alpha-Hydroxy-3beta-methyl-5alpha-pregnan-20-one.

**Chemical structure:**

![Chemical Structure Image]

**Molecular Formula:** C_{22}H_{36}O_{2}

**Pharmacological class / Application:** Steroid

**CAS-RN:** 38398-32-2

**International status:**

US: Ganaxolone is not listed in 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: The substance is not listed specifically in the schedules to the CDSA. The substance is a synthetic analogue of allopregnanolone and has been reported in the scientific literature to be useful for the treatment of epilepsy. It has not been reported to display any anabolic activity nor derived from anabolic steroid and therefore is not captured under item 23 “Anabolic steroids and their derivatives” of Schedule IV to the CDSA.

**Recommendation:** Ganaxolone is not included in the schedules to the CDSA is not a controlled substance.

**Date:** January 24th, 2012.