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

Substance:  Delta4-Tibolone-\(^{13}\)CD3 3-ethylene ketal

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 has not been reported in the literature to be a derivative of tibolone or delta4-tibolone, nor display any anabolic activity.

Prepared by: ___________________________  Date: Nov 17\(^{th}\) 2010
Evelyn Soo

Verified by: ___________________________  Date: ____________
Marianne Tang

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:** Delta4-Tibolone-$^{13}$CD3 3-ethylene ketal

**Drug Name Status:** Delta4-Tibolone-$^{13}$CD3 3-ethylene ketal is the common name.

**Chemical Name:** (7alpha,17alpha)-17-Hydroxy-7-(methyl-$^{13}$C,d3)-19-norpregn-4-en-20-yn-3-one, cyclic 1,2-ethanediyl acetal

**Chemical structure:**

![Chemical structure diagram](image)

**Molecular Formula:** $C_{22}^{13}$CH$_{29}$D$_3$O$_3$;

**Pharmacological class / Application:** Pharmaceutical-related substance

**CAS RN:** NONE

**International status:**

**US:** Delta4-Tibolone-$^{13}$CD3 3-ethylene ketal is not listed in the Schedules to the CSA and is not mentioned anywhere on the DEA website.

**United Nations:** Delta4-Tibolone-$^{13}$CD3 3-ethylene ketal 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:** Delta4-Tibolone-$^{13}$CD3 3-ethylene ketal is not listed specifically in the CDSA. The substance is a starting material in the preparation of the labelled form of delta4-tibolone, which is a metabolite of tibolone. However, delta4-Tibolone-$^{13}$CD3 3-ethylene ketal has not been shown in the scientific literature to be derived from tibolone nor delta4-tibolone and there are not reports that the substance displays any anabolic activity. Accordingly, delta4-Tibolone-$^{13}$CD3 3-ethylene ketal cannot be included under the heading “Anabolic steroids and their derivatives” of item 23 of Schedule IV to the CDSA.

Recommendation: Delta4-Tibolone-$^{13}$CD3 3-ethylene ketal is not included under item 23 of Schedule IV to the CDSA and is not a controlled substance.

November 17th 2010