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

Substance: I - 7beta-Tibolone
II - Tibolone-\textsuperscript{13}CD\textsubscript{3} 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 substances have not been reported in the literature to be derivatives of tibolone nor display any anabolic activity.

Prepared by: _______________________________ Date: Nov 17\textsuperscript{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:**
I - 7beta-Tibolone  
II - Tibolone-\(^{13}\)CD3 3-ethylene ketal

**Drug Name Status:**
I - 7beta-Tibolone  
II - Tibolone-\(^{13}\)CD3 3-ethylene ketal

**Chemical Name:**
I - (7beta,17alpha)-17-Hydroxy-7-methyl-19-norpregn-5(10)-en-20-yn-3-one  
II - (7alpha,17alpha)-17-Hydroxy-7-(Methyl-\(^{13}\)C,d3)-19-norpregn-5(10)-en-20-yn-3-one, cyclic 1,2-ethanediyl acetal

**Chemical structure:**

![Chemical structure of I and II](image)

**Molecular Formula:** I - C\(_{21}\)H\(_{29}\)O\(_2\); II - C\(_{22}\)\(^{13}\)CH\(_{29}\)D\(_3\)O\(_3\)

**Pharmacological class / Application:** Steroid

**CAS RN:** I - 100239-44-9; II - NONE

**International status:**

**US:** 7beta-Tibolone and tibolone-\(^{13}\)CD3 3-ethylene ketal are not listed in the Schedules to the CSA and are not mentioned anywhere on the DEA website.

**United Nations:** 7beta-Tibolone and tibolone-\(^{13}\)CD3 3-ethylene ketal are 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:** 7beta-Tibolone and tibolone\(^{13}\)CD3 3-ethylene ketal are not listed specifically in the CDSA. 7beta-Tibolone is an epimer of tibolone whereby the methyl group is in the beta position rather than the alpha position. The substance is claimed to be an impurity related to the
synthesis of tibolone and there is no evidence in the scientific literature to indicate that 7-beta tibolone displays any anabolic activity nor that it is derived from tibolone. Tibolone$^{13}$CD3 3-ethylene ketal is the labelled form of tibolone-3-ethylene ketal and is claimed to be a starting material used in the synthesis of tibolone$^{13}$C,d3. While tibolone$^{-13}$C,d3 would be considered controlled under item 23(41) of Schedule IV to the CDSA, the substance also has not been shown in the scientific literature to be derived from tibolone nor to display any anabolic activity. Accordingly, 7beta-Tibolone and 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: 7beta-Tibolone and tibolone$^{13}$CD3 3-ethylene ketal are not included under item 23 of Schedule IV to the CDSA and are not controlled substances.

November 17th 2010