



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

Substance: I - 7beta-Tibolone
II - Tibolone-13CD3 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 [x]

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: Evelyn Soo Date: Nov 17th 2010

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

This status was requested by: "third party information removed as per agreement with applicant"

Drug Status Report

Drug:

I - 7beta-Tibolone

II - Tibolone-¹³CD₃ 3-ethylene ketal

Drug Name Status:

I - 7beta-Tibolone

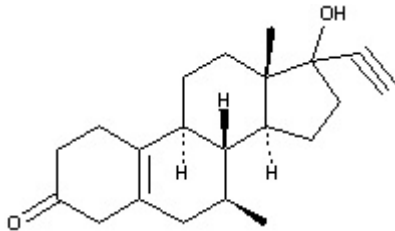
II - Tibolone-¹³CD₃ 3-ethylene ketal

Chemical Name:

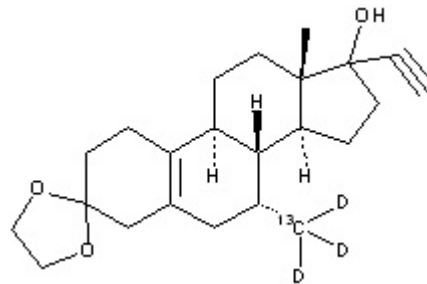
I - (7beta,17alpha)-17-Hydroxy-7-methyl-19-norpregn-5(10)-en-20-yn-3-one

II - (7alpha,17alpha)-17-Hydroxy-7-(Methyl-¹³C,d₃)-19-norpregn-5(10)-en-20-yn-3-one, cyclic 1,2-ethanediyl acetal

Chemical structure:



I



II

Molecular Formula: I - C₂₁H₂₈O₂; II - C₂₂¹³CH₂₉D₃O₃

Pharmacological class / Application: Steroid

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

International status:

US: 7beta-Tibolone and tibolone-¹³CD₃ 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-¹³CD₃ 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-¹³CD₃ 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-¹³C₃ 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-¹³C₃. While tibolone-¹³C₃ 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-¹³C₃ 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-¹³C₃ 3-ethylene ketal are not included under item 23 of Schedule IV to the CDSA and are not controlled substances.

November 17th 2010