



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

Substance: Delta4-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

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: 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"

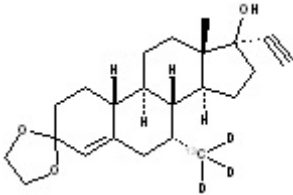
Drug Status Report

Drug: Delta4-Tibolone-¹³CD3 3-ethylene ketal

Drug Name Status: Delta4-Tibolone-¹³CD3 3-ethylene ketal is the common name.

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

Chemical structure:



Molecular Formula: C₂₂¹³CH₂₉D₃O₃

Pharmacological class / Application: Pharmaceutical-related substance

CAS RN: NONE

International status:

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

November 17th 2010