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

Substance: I - 3,17-Di-O-acetyl Androsta-5,14,16-triene-3β,17-diol; II - 3-O-Acetyl 5,14-Androstadiene-3β,17β-diol; III - 3-O-Acetyl-17-O-tert-butyldimethylsilyl 5,14-Androstadiene-3β,17β-diol; IV - 3,17-Bis-O-(tert-butyldimethylsilyl) 5,14-Androstadiene-3β,17β-diol; V - 17-O-tert-Butyldimethylsilyl 5,14-Androstadiene-3β,17β-diol; VI - 3β-Methoxy-5,14-androstadiene-17β-ol; VII - (3β,5αa,6β,15αa,17β)-17-tert-Butyldimethylsilyloxy-6-methoxy-3,5-cycloandrostan-15-ol; VIII - (3β,15αa,17β)-15,17-Bis-O-(tert-butyldimethylsilyloxy) Androst-5-en-3-ol 3-O-Acetate; IX - (3β,15αa,17β)-15,17-Bis-O-(tert-butyldimethylsilyloxy) Androst-5-en-3-ol

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 are synthetic intermediates of 15alpha-tesosterone and are not derivatives of an anabolic steroid nor display any anabolic activity.

Prepared by: ________________________________ Date: Nov 10th 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:  
I - 3,17-Di-O-acetyl Androsta-5,14,16-triene-3β,17-diol  
II - 3-O-Acetyl 5,14-Androstadiene-3β,17β-diol  
III - 3-O-Acetyl-17-O-tert-butyldimethylsilyl 5,14-Androstadiene-3β,17β-diol  
IV - 3,17-Bis-O-(tert-Butyldimethylsilyl) 5,14-Androstadiene-3β,17β-diol  
V - 17-O-tert-Butyldimethylsilyl 5,14-Androstadiene-3β,17β-diol  
VI - 3β-Methoxy-5,14-androstadiene-17β-ol  
VII - (3β,5αa,6β,15αa,17β)-17-tert-Butyldimethylsilyloxy-6-methoxy-3,5-cycloandrostan-15-ol  
VIII - (3β,15αa,17β)-15,17-Bis-O-(tert-butyldimethylsilyloxy) Androst-5-en-3-ol 3-O-Acetate  
IX - (3β,15αa,17β)-15,17-Bis-O-(tert-butyldimethylsilyloxy) Androst-5-en-3-ol

Drug Name Status:  
I - 3,17-Di-O-acetyl Androsta-5,14,16-triene-3β,17-diol  
II - 3-O-Acetyl 5,14-Androstadiene-3β,17β-diol  
III - 3-O-Acetyl-17-O-tert-butyldimethylsilyl 5,14-Androstadiene-3β,17β-diol  
IV - 3,17-Bis-O-(tert-Butyldimethylsilyl) 5,14-Androstadiene-3β,17β-diol  
V - 17-O-tert-Butyldimethylsilyl 5,14-Androstadiene-3β,17β-diol  
VI - 3β-Methoxy-5,14-androstadiene-17β-ol  
VII - (3β,5αa,6β,15αa,17β)-17-tert-Butyldimethylsilyloxy-6-methoxy-3,5-cycloandrostan-15-ol  
VIII - (3β,15αa,17β)-15,17-Bis-O-(tert-butyldimethylsilyloxy) Androst-5-en-3-ol 3-O-Acetate  
IX - (3β,15αa,17β)-15,17-Bis-O-(tert-butyldimethylsilyloxy) Androst-5-en-3-ol

Chemical Name:  
I - 3,17-Di-O-acetyl Androsta-5,14,16-triene-3β,17-diol  
II - 3-O-Acetyl 5,14-Androstadiene-3β,17β-diol  
III - 3-O-Acetyl-17-O-tert-butyldimethylsilyl 5,14-Androstadiene-3β,17β-diol  
IV - 3,17-Bis-O-(tert-Butyldimethylsilyl) 5,14-Androstadiene-3β,17β-diol  
V - 17-O-tert-Butyldimethylsilyl 5,14-Androstadiene-3β,17β-diol  
VI - 3β-Methoxy-5,14-androstadiene-17β-ol
VII - (3β,5αa,6β,15αa,17β)-17-tert-Butyldimethylsilyloxy-6-methoxy-3,5-cycloandrostan-15-ol

VIII - (3β,15αa,17β)-15,17-Bis-O-(tert-butyldimethylsilyloxy) Androst-5-en-3-ol 3-O-Acetate

IX - (3β,15αa,17β)-15,17-Bis-O-(tert-butyldimethylsilyloxy) Androst-5-en-3-ol

Chemical structure:
**Molecular Formula:** I - C_{23}H_{32}O_4; II - C_{21}H_{30}O_3; III - C_{27}H_{44}O_4Si; IV - C_{32}H_{59}O_2Si_2; V - C_{25}H_{42}O_2Si; VI - C_{20}H_{30}O_2; VII - C_{26}H_{46}O_3Si; VIII - C_{33}H_{60}O_4Si_2; IX - C_{31}H_{58}O_3Si_2

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

**CAS-RN:** I - 34635-42-2; II 61252-30-0; III - 61252-31-1; IV - NONE; V - 61252-32-2; VI - NONE; VII - 61252-65-5; VIII - 65429-24-5; IX - 65429-25-6

**International status:**

US: The above nine substances are not listed specifically in the CDSA and are not mentioned on the DEA website.

United Nations: The substances 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: The above nine substances are intermediates involved in the 13-step synthesis of 15alpha-testosterone from dehydroepiandrosterone. While both 15alpha-testosterone and epiandrosterone are currently controlled under item 23 of Schedule IV to the CDSA under the heading “Anabolic steroids and their derivatives including”, none of the above substances are derived directly from epiandrosterone and they have not been reported in the literature to display any anabolic activity. Therefore the substances are not included under item 23 of Schedule IV to the CDSA.

**Recommendation:** 3,17-Di-O-acetyl Androsta-5,14,16-triene-3β,17-diol, 3-O-Acetyl 5,14-Androstadiene-3β,17β-diol, 3-O-Acetyl-17-O-tert-butyldimethylsilyl 5,14-Androstadiene-3β,17β-diol, 3,17-Bis-O-(tert-Butyldimethylsilyl) 5,14-Androstadiene-3β,17β-diol, 17-O-tert-Butyldimethylsilyl 5,14-Androstadiene-3β,17β-diol, 3β-Methoxy-5,14-Androstadiene-17β-ol, (3β,5α,6β,15α,17β)-17-tert-Butyldimethylsilyloxy-6-methoxy-3,5-cycloandrostan-15-ol, (3β,15α,17β)-15,17-Bis-O-(tert-butyldimethylsilyloxy) Androst-5-en-3-ol, 3-O-Acetate and (3β,15α,17β)-15,17-Bis-O-(tert-butyldimethylsilyloxy) Androst-5-en-3-ol are not included in Schedule IV to the CDSA and are not controlled substances.

**Date:** 10 November 2010