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

Substance: 5alpha-dihydrotestosterone undecanoate

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 is a derivative androstanolone and therefore included under item 23(2) of Schedule IV to the CDSA.

Prepared by: ____________________________ Date: Nov 15th 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: 5alpha-dihydrotestosterone undecanoate

Drug Name Status: 5alpha-dihydrotestosterone undecanoate

Chemical Name: (5alpha,17beta)-17-[(1-Oxoundecyl)oxy]androstan-3-one

Chemical structure:

Molecular Formula: $C_{30}H_{50}O_3$

Pharmacological class / Application: Steroid derivative

CAS-RN: 6804-12-2

International status:

US: 5alpha-dihydrotestosterone undecanoate is not currently listed in the schedules to US Controlled Substances Act. However, the parent steroid, 5alpha-dihydrotestosterone is controlled under Schedule III to the CSA.

United Nations: The substance 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: 5alpha-dihydrotestosterone undecanoate is not listed specifically in the CDSA. However, the substance is a derivative of 5alpha-dihydrotestosterone which is listed as item 23(2) “Androstanolone (17b-hydroxy-5a-androstane-3-one)” in Schedule IV to the CDSA under the heading “Anabolic steroids and their derivatives including:”. Accordingly, the substance is considered to be included under item 23(2) of Schedule IV to the CDSA

Recommendation: 5alpha-dihydrotestosterone undecanoate is included under item 23(2) of Schedule IV to the CDSA and is a controlled substance.

Date: 15 November 2010