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

Substance: 3-alpha-hydroxy-5-beta-androstan-11,17-dione sulfate (11-Ketoetiocholanolone sulfate)

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 drug is currently not listed specifically on the CDSA.
- There is no information available that suggests that 11-ketoetiocholanolone is a derivative of the anabolic steroids.
- Roelfsema et al.\(^1\) exclude 11-ketoetiocholanolone from the androgen metabolites while including etiocholanolone and classify it as a cortisol metabolite. Cortisol is not and anabolic steroid.
- It follows that derivatives of 3-alpha-hydroxy-5-beta-androstan-11,17-dione such as 3-alpha-Hydroxy-5-beta-androstan-11,17-dione sulfate are also not controlled substances.

Supporting document(s) attached: X

Prepared by: ______________ Date: 2005-06-23
TIANA BRANCH

Verified by: See email Date: 2005-06-23
MICHAEL LEBELLE

Approved by: ______________ Date: __________
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

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Drug Status Report

**Drug**: 3-alpha-hydroxy-5-beta-androstan-11,17-dione

**Drug Name Status**: 11-Ketoetiocholanolone is the common name

**Chemical Name**: (3alpha,5beta)-3-hydroxy-androstan-11,17-dione

**Molecular Formula**: C_{19}H_{28}O_{3}

**Pharmacological class / Application**: metabolite of cortisol

**International status**:

US: The drug is not currently listed on the US Controlled Substances Act and is not mentioned on the DEA website.

United Nations: The drug is not listed on the Yellow List - List of Narcotic Drugs under International Control. The drug is not listed on the Green List - List of Psychotropic Substances under International Control

Canadian Status: The drug is currently not listed specifically on the CDSA. There is no information available that suggests that 11-ketoetiocholanolone is a derivative of the anabolic steroids. Roelfsema et al.² exclude 11-ketoetiocholanolone from the androgen metabolites while including etiocholanolone and classify it as a cortisol metabolite. Cortisol is not and anabolic steroid.

Recommendation: 3-alpha-Hydroxy-5-beta-androstan-11,17-dione is not included in the Schedules to the CDSA and is not a controlled substance. It follows that derivatives of 3-alpha-hydroxy-5-beta-androstan-11,17-dione such as 3-alpha-Hydroxy-5-beta-androstan-11,17-dione glucuronide and 3-alpha-Hydroxy-5-beta-androstan-11,17-dione sulfate are also not controlled substances.

June 23, 2005