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

Substance: 17beta-Hydroxyexemestane

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 metabolite of exemestane and does not display any anabolic activity.

Prepared by: ________________________________  Date: __________
Evelyn Soo

Verified by: ________________________________  Date: __________
Mark Kozlowski

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

This status was requested by: “third party information removed as per agreement with applicant”
Drug Status Report

Drug: 17beta-Hydroxyexemestane

Drug Name Status: 17beta-Hydroxyexemestane is the common name.

Chemical Name: (17beta)-17-Hydroxy-6-methyleneandrosta-1,4-diene-3-one

Chemical structure:

Molecular Formula: C_{20}H_{26}O_{2}

CAS-RN: 122370-91-6

Pharmacological class / Application: Steroid

International status:

US: 17beta-Hydroxyexemestane is not listed on the schedules to the US Controlled Substances Act and is not mentioned anywhere on the DEA website.

United Nations: The substance is not listed on the Yellow List - List of Narcotic Drugs under International Control, the Green List - List of Psychotropic Substances under International Control, nor the Red List - List of Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances Under International Control.

Canadian Status: 17beta-Hydroxyexemestane is not listed in the schedules to the CDSA. The substance is the primary urinary metabolite of exemestane\(^1\), a substance that was previously reviewed not included under “Anabolic steroids and their derivatives” of item 23 of Schedule IV to the CDSA, on the basis that it is not anabolic steroid. Given that exemestane is not controlled under the CDSA and that 17beta-Hydroxyexemestane has not been reported to display any anabolic activity, the substance cannot included under item 23 of Schedule IV to the CDSA.

Recommendation: 4 17beta-hydroxyexemestane is not included in the Schedules to the CDSA and is not a controlled substance.

Date: Sept 15th, 2011

\(^1\)Cavalcanti, G. Et al. Detection of new urinary exemestane metabolites by gas chromatography coupled to mass spectrometry, Steroids, 76:1010-1015.