Health Canada Santé Canada

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

Substance: 16alpha-Hydroxyestrone

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 shown in the scientific literature to display anabolic activity, and is not included under item 23 of Schedule IV to the CDSA.

Prepared by: _____ Date: August 16th 2011
Vincent Marleau

Verified by: _____ Date: _____
Mark Kozlowski

Approved by: _____ Date: _____
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Eva Roig

Drug Status Report

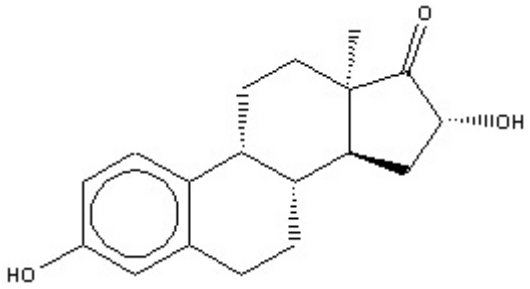
Drug: 16alpha-Hydroxyestrone

Drug Name Status: 16alpha-Hydroxyestrone is the common name.

Chemical Name: Estra-1,3,5(10)-trien-17-one, 3,16-dihydroxy-, (16alpha)-

Other Names: Hydroxyestrone-16alpha; 3,16alpha-Dihydroxyestra-1,3,5(10)-trien-17-one.

Chemical structure:



Molecular Formula: $C_{18}H_{22}O_3$

Pharmacological class / Application: Steroid

CAS-RN: 566-76-7

International status:

US: 16alpha-Hydroxyestrone is not listed specifically in 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: 16alpha-Hydroxyestrone is not currently listed in the CDSA. The substance is a derivative of estradiol and is known for its high estrogenic activity and its role in the development of breast cancer[1]. Since 16alpha-hydroxyestrone does not display

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[1]Muti. P., et al(2000). Estrogen metabolism and risk of breast cancer: A prospective study of the 2:16[alpha]-Hydroxyestrone ratio in premenopausal and postmenopausal women. Epidemiology **11**:635-640.

any anabolic activity and is not a derivative of an anabolic steroid, it cannot be included under the heading “Anabolic steroids and their derivatives:” of item 23 of Schedule IV to the CDSA.

Recommendation: 16alpha-Hydroxyestrone is not included under the Schedules to the CDSA and is not a controlled substance.

Date: 16 August 2011