



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

Substance: I - 9alpha-Fluoro-18-nor-17,17-dimethylandrosta-4,13-diene-11beta-ol-3-one
II - 9alpha-Fluoro-17alpha-methylandrosta-4-ene-3alpha,6beta,11beta-tetrol

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

Controlled [checked]
Not Controlled [unchecked]

under the schedules of the Controlled Drugs and Substances Act (CDSA) for the following reason(s):

- The substances are metabolites of the anabolic steroid fluoxymesterone and therefore are included under item 23 of Schedule IV to the CDSA.

Prepared by: Evelyn Soo Date: Dec 16th 2010

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

This status was requested by: "third party information removed as per agreement with applicant"

Drug Status Report

Drug: I - 9alpha-Fluoro-18-nor-17,17-dimethylandrosta-4,13-diene-11beta-ol-3-one
II - 9alpha-Fluoro-17alpha-methylandrosta-4-ene-3alpha,6beta,11beta-tetrol

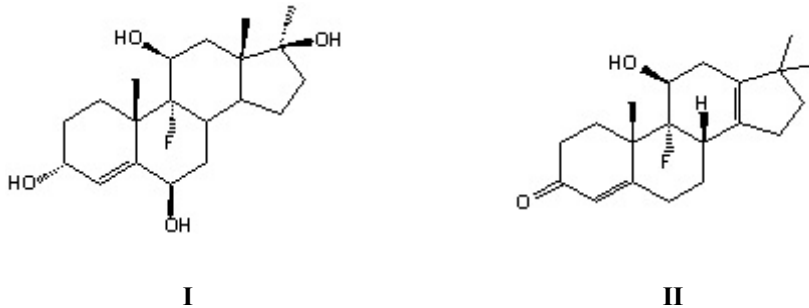
Drug Name Status:

I - 9alpha-Fluoro-18-nor-17,17-dimethylandrosta-4,13-diene-11beta-ol-3-one
II - 9alpha-Fluoro-17alpha-methylandrosta-4-ene-3alpha,6beta,11beta-tetrol are the common names

Chemical Name:

I - 9alpha-Fluoro-18-nor-17,17-dimethylandrosta-4,13-diene-11beta-ol-3-one
II - 9alpha-Fluoro-17alpha-methylandrosta-4-ene-3alpha,6beta,11beta-tetrol

Chemical structure:



Molecular Formula: I - $C_{20}H_{31}FO_4$; II - $C_{20}H_{27}FO_2$

Pharmacological class / Application: Steroid metabolites

CAS-RN: I; II - None

International status:

US: 9alpha-Fluoro-18-nor-17,17-dimethylandrosta-4,13-diene-11beta-ol-3-one and 9alpha-fluoro-17alpha-methylandrosta-4-ene-3alpha,6beta,11beta-tetrol not listed specifically in the Schedules to the CSA and are not mentioned anywhere on the DEA website.

United Nations: The substances are not listed specifically on the Yellow List - List of Narcotic Drugs under International Control nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: An earlier review of 9alpha-fluoro-18-nor-17,17-dimethylandrosta-4,13-diene-11beta-ol-3-one and 9alpha-fluoro-17alpha-methylandrosta-4-ene-3alpha,6beta,11beta-tetrol was made in 2002 and the steroids were considered not controlled under the CDSA. However, a recent status request for 9alpha-fluoro-18-nor-17,17-dimethylandrosta-4,13-diene-11beta-ol-3-one prompted a secondary review of these substances as these steroids are in fact well-

established in the scientific literature to be metabolites of fluoxymesterone. Fluoxymesterone is currently listed as sub-item 23(16) in Schedule IV to the CDSA under the heading “Anabolic steroids and their derivatives including:” and as metabolites of fluoxymesterone, the substances must be included under sub-item 23(16) of Schedule IV to the CDSA.

Recommendation: 9alpha-Fluoro-18-nor-17,17-dimethylandrosta-4,13-diene-11beta-ol-3-one and 9alpha-fluoro-17alpha-methylandrosta-4-ene-3alpha,6beta,11beta-tetrol are included under item 23 of Schedule IV to the CDSA and are controlled substances.

Date: 16 December 2010