



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

Substance: Dronabinol related substances

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

Controlled X
Not Controlled []

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

- There are four substances in question, and they are currently not listed specifically on the CDSA.
Item 1 of Schedule II to the CDSA includes, "Cannabis, its preparations, derivatives and similar synthetic preparations."
All substances are similar synthetic preparations of derivatives of cannabis and included in item 1 of Schedule II to the CDSA

Supporting document(s) attached: X

Prepared by: _____ Date: _____
SHEREEN KHAN

Verified by: _____ Date: _____
See email
MICHAEL LEBELLE

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

Drug Status Report

Drug: Dronabinol related substances

This status report was prompted by a request from a manufacturer of dronabinol. The four substances are pharmaceutical related compounds for dronabinol. Dronabinol is the pharmaceutical name assigned to delta9-tetrahydrocannabinol, the major psychoactive component of cannabis.

Drug Name Status: The common names of the four compounds are:

I- dronabinol impurity D

II - dronabinol impurity X

III - dronabinol impurity A; cannabidiol

IV - dronabinol impurity C

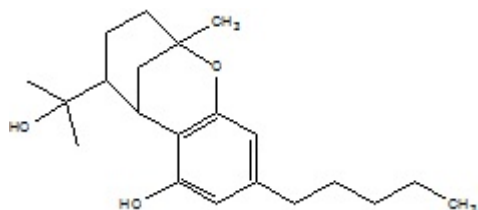
Chemical Name: I- 12-(1-Hydroxy-1-methylethyl)-9-methyl-5-pentyl-8-oxa-tricyclo[7.3.1.0*2,7*]trideca-2,4,6-trien-3-ol

II - 12-Isopropylidene-9-methyl-5-pentyl-8-oxa-tricyclo[7.3.1.0*2,7*]trideca-2,4,6-trien-3-ol

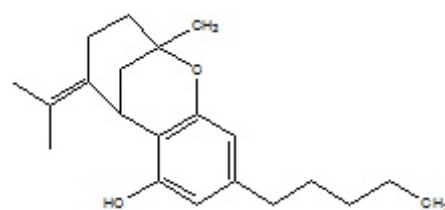
III- 2-(6-Isopropenyl-3-methylcyclohex-2-enyl)-5-pentylbenzene-1,3-diol

IV- 5a-Isopropyl-8-methyl-3-pentyl-5a,6,7,9a-tetrahydro-dibenzofuran-1-ol

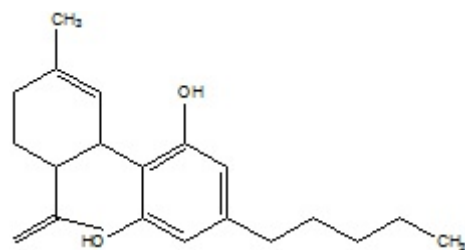
Chemical structure:



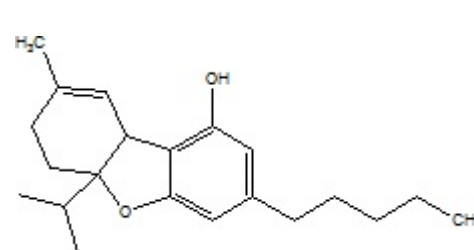
I



II



III



IV

Molecular Formula: I- $C_{21}H_{32}O_3$

II- $C_{21}H_{30}O_2$

III- $C_{21}H_{30}O_2$

IV- $C_{21}H_{30}O_2$

Pharmacological/chemical class / Application: cannabinoid

International status:

US: The drugs are not currently listed on the US Controlled Substances Act and are not mentioned on the DEA website. However, the tetrahydrocannabinols- there are several isomers-are listed on Schedule I to the CSA. The analogue provision of the CSA, "controlled substance analogue" means a substance- (I) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II" therefore applies. The DEA would have to confirm the status of these substances under the CSA.

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

Canadian Status: The chemicals are currently not listed specifically on the CDSA. Item 1 of Schedule II to the CDSA includes, "Cannabis, its preparations, derivatives and similar synthetic preparations." This item includes, in addition to the well known components of cannabis, other substances similar in structure to the classical cannabinoids. Substance III also known as cannabidiol is subitem 1(3) of Schedule II. On August 4, 2005 OCS made a decision that ajulemic acid and some related substances were included in Schedule II to the CDSA because they were "similar synthetic preparations" within the meaning of the heading to item 1 of Schedule II. Substances I, II and IV are also synthetic preparations similar to the cannabinoids.

Recommendation: Substance III, cannabidiol, is currently listed in item 1 of Schedule II to the CDSA and is a controlled substance. Substances I, II and IV are similar synthetic preparations of derivatives of cannabis and included in item 1 of Schedule II to the CDSA. They are controlled substances.

February 18, 2006