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

Substance: Flibanserin

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 an antidepressant drug and is not considered to be a narcotic of the benzimidazole-type.

Prepared by: _______________________________ Date: Nov 15th 2010

Evelyn Soo

Verified by: _______________________________ Date: __________

Marianne Tang

Approved by: _______________________________ Date: __________

DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

**This status was requested by:** Inspectorate
Drug Status Report

Drug: Flibanserin

Drug Name Status: Flibanserin is the common (INN) name.

Chemical Name: 1,3-Dihydro-1-(2-(4-(3-(trifluoromethyl)phenyl)-1-piperazinyl)ethyl)-2H-benzimidazol-2-one

Other Names: 1-(2-(4-(3-Trifluoromethylphenyl)piperazin-1-yl)ethyl)benzimidazol(1H)-2-one; 1-(2-(4-(alpha, alpha, alpha-Trifluoro-m-tolyl)-1-yl)ethyl)-2-benzimidazolinone;

Chemical structure:

\[
\text{Bezitramide}
\]

Molecular Formula: \( C_{20}H_{21}N_4O \)

Pharmacological class / Application: Anti-depressant

CAS-RN: 167933-07-5

International status:

US: Flibanserin is not listed specifically in the schedules to the CSA 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 nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Flibanserin is not listed specifically in the CDSA. The drug shows some structural similarity to the potent narcotic analgesic, bezitramide, which is currently listed as item 13(3) under Schedule I to the CDSA under the heading “Benzimidazoles, their salts, derivatives and salts of derivatives including:”. However, the pharmacological properties of flibanserin is different to that of bezitramide, in that it has been reported to have a prefrential affinity for the
serotonin 5-HT₁₅, dopamine D₄ and serotonin 5-HT₂₅ receptors and display antidepressant-like activity. Flibanserin has more recently been reported to show potential in the treatment of sexual dysfunction in women.

It is noteworthy that not all benzimidazoles are included inder item 13 of Schedule I. There is a large chemical family of benzimidazoles used to treat worm infections in man and animals for example, mebendazole, and these substances are not included under item 13 of Schedule I to the CDSA. Therefore, while flibanserin contains a benzimidazole in its structure, the substance is not considered to be a narcotic and therefore is not captured under item 13 of Schedule I to the CDSA.

**Recommendation:** Flibanserin is not included in any of the schedules to the CDSA and is not a controlled substance.

**Date:** 15 November 2010

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