



## 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: \_\_\_\_\_  
Evelyn Soo

Date: Nov 15<sup>th</sup> 2010

Verified by: \_\_\_\_\_  
Marianne Tang

Date: \_\_\_\_\_

Approved by: \_\_\_\_\_  
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

Date: \_\_\_\_\_

**This status was requested by:** Inspectorate

## Drug Status Report

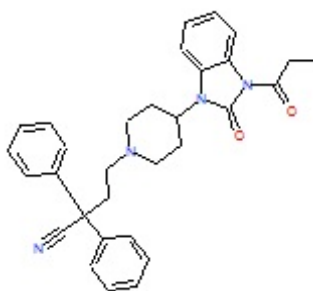
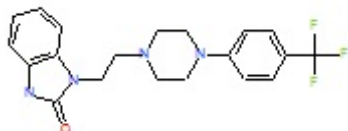
**Drug:** Flibanserin

**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:**



**Bezitramide**

**Molecular Formula:** C<sub>20</sub>H<sub>21</sub>N<sub>4</sub>O

**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 preferential affinity for the

serotonin 5-HT<sub>1A</sub>, dopamine D4 and serotonin 5-HT<sub>2A</sub> receptors and display antidepressant-like activity<sup>1</sup>. Flibanserin has more recently been reported to show potential in the treatment of sexual dysfunction in women<sup>2</sup>.

It is noteworthy that not all benzimidazoles are included under 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

---

<sup>1</sup>Borsini, *Fet al.* (2002) Pharmacology of flibanserin, *CNS Drug Rev.* **8**:117-142.

<sup>2</sup>Kennedy, S. (2010) Flibanserin: initial evidence of efficacy on sexual dysfunction, in patients with major depressive disorder, *J. Sexual Med.* **7**:3449-3459.