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

Substance: 5-Fluoro-3-(4-piperidinyl)-1,2-benzisoxazole hydrochloride

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 intermediate in the synthesis of 5-fluoro risperidone and is not structurally similar to any of the substances included in the schedules to the CDSA.

Prepared by: ________________________________ Date: April 18th 2011

Evelyn Soo

Verified by: ________________________________ Date: __________

Kim Barber

Approved by: ________________________________ Date: __________

DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: “third party information removed as per agreement with applicant”
Drug Status Report

**Drug:** 5-Fluoro-3-(4-piperidinyl)-1,2-benzisoxazole hydrochloride

**Drug Name Status:** 5-Fluoro-3-(4-piperidinyl)-1,2-benzisoxazole hydrochloride is the common name.

**Chemical Name:** 4-(5-Fluoro-1,2-benzisoxazol-3-yl)piperidine hydrochloride

**Chemical structure:**

![Chemical structure](image)

**Molecular Formula:** C₁₂H₁₃FN₂O.HCl

**Pharmacological class / Application:** Pharmaceutical-related substance

**CAS-RN:** 84163-16-6

**International status:**

US: 5-Fluoro-3-(4-piperidinyl)-1,2-benzisoxazole hydrochloride is not listed in the 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 nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: 5-Fluoro-3-(4-piperidinyl)-1,2-benzisoxazole hydrochloride is not listed in the schedules to the CDSA. The substance is an intermediate relating to the synthesis of 5-fluoro risperidone, which is a synthetic impurity of risperidone. Risperidone is an antipsychotic drug used for the treatment of schizophrenia and is currently regulated under Schedule F to the *Food and Drugs Regulations*. 5-Fluoro-3-(4-piperidinyl)-1,2-benzisoxazole hydrochloride is not structurally similar to any the substances included in schedules to the CDSA.

**Recommendation:** 5-Fluoro-3-(4-piperidinyl)-1,2-benzisoxazole hydrochloride is not included in the Schedules to the CDSA is not a controlled substance.

**Date:** 18 April 2011