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

Substance: \(\alpha\)-hydroxy fentanyl

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 a metabolite of fentanyl and contains the core structure of the fentanyls. It is therefore included under item 16 of Schedule I to the CDSA.

Prepared by: ______________________________ Date: Nov 10\(^{th}\) 2010
Evelyn Soo

Verified by: ______________________________ Date: ____________
Marianne Tang

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:**  \( \omega \)-Hydroxy fentanyl

**Drug Name Status:** \( \omega \)-Hydroxy fentanyl is the common name.

**Chemical Name:** 3-hydroxy-N-(1-phenethyl-4-piperidyl)-N-phenyl-propanamide

**Chemical structure:**

![Chemical structure of \( \omega \)-Hydroxy fentanyl]

**Molecular Formula:** \( \text{C}_{22}\text{H}_{28}\text{N}_{2}\text{O}_{2} \)

**Pharmacological class / Application:** Metabolite of fentanyl

**CAS-RN:** 83708-11-6

**International status:**

**US:** The substance is not currently listed in the schedules to the US Controlled Substances Act. However, the substance may be controlled due to the analogue provision of the CSA.

**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:** \( \omega \)-Hydroxy fentanyl has been reported in the scientific literature to be a major metabolite of fentanyl\(^1\) and is not currently listed in the CDSA. In addition to being a metabolite of fentanyl and hence considered a derivative of fentanyl, the substance contains the core structure of the fentanyls, as shown below:

![Core structure of fentanyls]

\( R = \text{ethyl group substituted variously at the 1 and 2 position} \)

\( R_1 = \text{hydrogen, methoxymethyl or carboxylate alkyl ester} \)

\( R_2 = \text{phenyl or substituted phenyl} \)

\( R_3 = \text{alkyl} \)

\( R_4 = \text{hydrogen or alkyl} \)

\(^1\)Higashikawa, Y. And Suzuki, S. (2008) Studies on 1-(2-phenethyl)-4-(N-Propionylanilino)piperidine (fentanyl) and its related compounds: novel metabolites in rat urine following injection of \( \alpha \)-methylfentanyl, one of the most abused typical desinger drugs, J. Health Sci. **54:** 629-637
Accordingly, ω-hydroxy fentanyl must be included under the family of fentanyls of item 16 of Schedule I to the CDSA.

**Recommendation:** ω-Hydroxy fentanyl is included under item 16 of Schedule IV to the CDSA and is a controlled substance.

**Date:** 10 November 2010