



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

Substance: ω-hydroxy fentanyl

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

Controlled [checked]
Not Controlled [unchecked]

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: Evelyn Soo Date: Nov 10th 2010

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

This status was requested by: "third party information removed as per agreement with applicant"

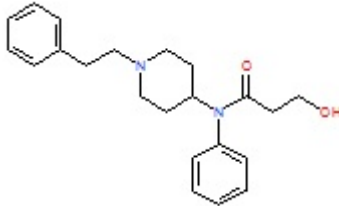
Drug Status Report

Drug: ω -Hydroxy fentanyl

Drug Name Status: ω -Hydroxy fentanyl is the common name.

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

Chemical structure:



Molecular Formula: $C_{22}H_{28}N_2O_2$

Pharmacological class / Application: Metabolite of fentanyl

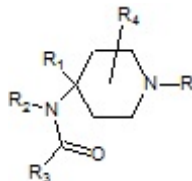
CAS-RN: 83708-11-6

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: ω -Hydroxy fentanyl has been reported in the scientific literature to be a major metabolite of fentanyl¹ 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:



R=ethyl group substituted variously at the 1 and 2 position

R₁=hydrogen, methoxymethyl or carboxylate alkyl ester

R₂=phenyl or substituted phenyl

R₃=alkyl

R₄=hydrogen or alkyl

¹Higashikawa, 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 α -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