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

Substance:  
I: ω-Hydroxynorfentanyl  
II: ω-Hydroxynorfentanyl O-beta-D-glucuronide  
III: ω-Hydroxyfentanyl O-beta-D-glucuronide

** SECONDARY REVIEW **

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

Controlled  X  Not Controlled  □

under the schedules of the Controlled Drugs and Substances Act (CDSA) for the following reason(s):

• The substances are derivatives of fentanyl and must be included under item 16 of Schedule I to the CDSA.

Prepared by: ___________________________ Date: ____________

Zack Li

Verified by: ___________________________ Date: ____________

Mark Kozlowski

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:  
I: ω-Hydroxynorfentanyl  
II: ω-Hydroxynorfentanyl O-beta-D-glucuronide  
III: ω-Hydroxyfentanyl O-beta-D-glucuronide

Drug Name Status:  
I: ω-Hydroxynorfentanyl  
II: ω-Hydroxynorfentanyl O-beta-D-glucuronide  
III: ω-Hydroxyfentanyl O-beta-D-glucuronide are the common names.

Chemical Name:  
I: 3-Hydroxy-N-phenyl-N-4-piperidinylpropanamide  
II: 3-Hydroxy-N-phenyl-N-4-piperidinylpropanamide O-beta-D-glucuronide  
III: 3-Hydroxy-N-(1-phenethyl-4-piperidyl)-N-phenyl-propanamide O-beta-D-glucuronide

Chemical structure:

Molecular Formula:  
I – C_{14}H_{20}N_{2}O_{2};  
II – C_{19}H_{28}N_{2}O_{7};  
III – C_{27}H_{26}N_{2}O_{7}

Pharmacological class / Application:  Pharmaceutical-related substances

CAS-RN:  
I – 83708-10-5;  
II – N/A;  
III – N/A

International status:

US: ω-Hydroxynorfentanyl, ω-Hydroxynorfentanyl O-beta-D-glucuronide and ω-Hydroxyfentanyl O-beta-D-glucuronide are not listed in the Schedules to the US Controlled Substances Act are not mentioned on the DEA website.

United Nations: The substances are not listed on the Yellow List - List of Narcotic Drugs under International Control, the Green List - List of Psychotropic Substances under International Control, nor the Red List - List of Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances under International Control.
Canadian Status:  ω-Hydroxynorfentanyl, ω-Hydroxynorfentanyl O-beta-D-glucuronide and ω-Hydroxyfentanyl O-beta-D-glucuronide are not listed specifically in the CDSA. However, ω-Hydroxynorfentanyl, ω-Hydroxynorfentanyl O-beta-D-glucuronide and ω-Hydroxyfentanyl O-beta-D-glucuronide are all metabolites of fentanyl. Fentanyl is currently listed as item 16 of Schedule I to the CDSA under the heading “Fentanyls, their salts, derivatives, and analogues and salts of derivatives and analogues, including.” As metabolites of fentanyl, ω-Hydroxynorfentanyl, ω-Hydroxynorfentanyl O-beta-D-glucuronide and ω-Hydroxyfentanyl O-beta-D-glucuronide are also captured under item 16 of Schedule I to the CDSA as derivatives of fentanyl.

**Recommendation:** ω-Hydroxynorfentanyl, ω-Hydroxynorfentanyl O-beta-D-glucuronide and ω-Hydroxyfentanyl O-beta-D-glucuronide are included under item 16 of Schedule I to the CDSA and are controlled substances.

**Date:** July 16th, 2012

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