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

Substance: O-Benzyl-N-tert-butoxycarbonyl α-hydroxy norfentanyl

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 does not contain the core structural features of the fentanyls and therefore cannot be included under item 16 of Schedule I to the CDSA.

Prepared by: _______________________________ Date: April 27th 2011
Evelyn Soo

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: O-Benzyl-N-tert-butoxycarbonyl ω-hydroxy norfentanyl

Drug Name Status: O-Benzyl-N-tert-butoxycarbonyl ω-hydroxy norfentanyl is the common name.

Chemical Name: 3-Benzylxy-N-phenyl-N-4-(N-tert-butoxycarbonylpiperidinylpropanamide)

Chemical structure:

Molecular Formula: C_{26}H_{34}N_{2}O_{4}

Pharmacological class / Application: Pharmaceutical-related substance

CAS-RN: NONE

International status:

US: O-Benzyl-N-tert-butoxycarbonyl ω-hydroxy norfentanyl 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, 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: O-Benzyl-N-tert-butoxycarbonyl ω-hydroxy norfentanyl is not listed in the CDSA. The substance is protected form of ω-hydroxy norfentanyl which was recently reviewed and concluded as not controlled under item 16 of Schedule I to the CDSA, on the basis that it does not have the the core structure of the fentanyls as shown below:

\[
\begin{align*}
&\text{where} \quad R = \text{ethyl group substituted variously at the 1 and 2 position} \\
&\text{R}_1 = \text{hydrogen, methoxymethyl or carboxylate alkyl ester} \\
&\text{R}_2 = \text{phenyl or substituted phenyl} \\
&\text{R}_3 = \text{alkyl} \\
&\text{R}_4 = \text{hydrogen or alkyl}
\end{align*}
\]
As such, O-Benzyl-N-tert-butoxycarbonyl $\omega$-hydroxy norfentanyl is also considered not to fall under the heading “Fentanyl, their salts, derivatives, and analogues and salts of derivatives and analogues, including:” of item 16 of Schedule I to the CDSA.

**Recommendation:** O-Benzyl-N-tert-butoxycarbonyl $\omega$-hydroxy norfentanyl is not included in the schedules to the CDSA and is not a controlled substance.

**Date:** 27 April 2011