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

Substance: N-(1-phenethyl-4-piperidyl)-N-phenyl-acetamide

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):

- N-(1-phenethyl-4-piperidyl)-N-phenyl-acetamide contains the root structure of the fentanyls and therefore is included under item 16 of Schedule I to the CDSA.

Prepared by: ___________________________ Date: July 27th 2010

Evelyn Soo

Verified by: ___________________________ Date: ________

Marianne Tang

Approved by: ___________________________ Date: ________

DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: A company wishing to synthesize fentanyl impurities.
Drug Status Report

Drug: N-(1-phenethyl-4-piperidyl)-N-phenyl-acetamide

Drug Name Status: Fentanyl impurity C is the common name.

Chemical Name: N-(1-phenethyl-4-piperidyl)-N-phenyl-acetamide

Chemical structure:

Molecular Formula: C_{21}H_{26}N_{2}O

CAS-RN: 3258-84-2

Pharmacological class / Application: pharmaceutical-related substance

International status:

US: The substance is not listed on the schedules to the CSA and is not mentioned on the DEA website.

United Nations: This 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: N-(1-phenethyl-4-piperidyl)-N-phenyl-acetamide is an impurity relating to the synthesis of fentanyl and can also be considered a structural analogue of fentanyl. A review of the current family of fentanyls revealed that substances included under item 16 of Schedule I to the CDSA all contain the following root structure:

\[ R = \text{ethyl group substituted variously at the 1 and 2 position} \]
\[ R_1 = \text{hydrogen, methoxymethyl or carboxylate alkyl ester} \]
\[ R_2 = \text{phenyl or substituted phenyl} \]
\[ R_3 = \text{alkyl} \]
\[ R_4 = \text{hydrogen or alkyl} \]

N-(1-phenethyl-4-piperidyl)-N-phenyl-acetamide clearly contains all the essential structural elements of the fentanyls and therefore, it would be included under the heading “Fentanyls,
their salts, derivatives, and analogues and salts of derivatives and analogues, including” of item 16 of Schedule I to the CDSA.

Recommendation: N-(1-phenethyl-4-piperidyl)-N-phenyl-acetamide is included under item 16 of Schedule I to the CDSA and is a controlled substance.

July 27th 2010