Health Canada Santé Canada

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

Substance: Propionanilide

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: May 24, 2011
Zack Li

Verified by: _____ Date: _____
Mark Kozlowski

Approved by: _____ Date: _____
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Wissam Sader, OCS

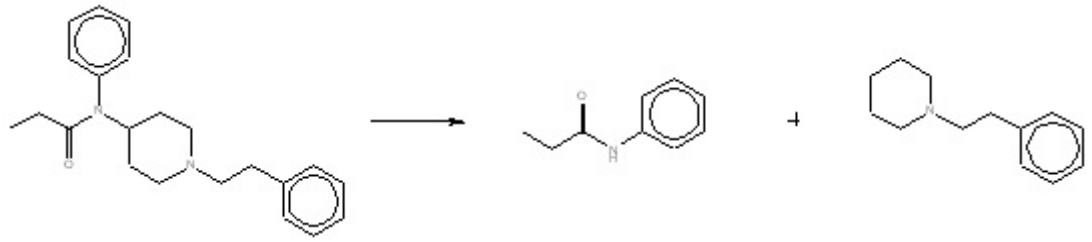
Drug Status Report

Drug: Propionanilide

Drug Name Status: Propionanilide is the common name.

Chemical Name: N-phenylpropionamide

Chemical structure:



Fentanyl ***Propionanilide*** ***N-1-(2-phenylethyl)-4-piperdinyl***

Molecular Formula: $C_9H_{11}NO$

CAS RN: 620-71-3

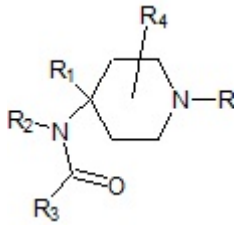
Pharmacological class / Application: Pharmaceutical-related substance

International status:

US: Propionanilide is not listed on the schedules to the US Controlled Substances Act and is not mentioned anywhere on the DEA website. However fentanyl, of which propionanilide is a degradation product, is controlled under the CSA.

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: Propionanilide is not listed in the schedules to the CDSA. The substance has been reported in the scientific literature to be a degradation product of fentanyl[1], which is currently controlled under item 16(5) of Schedule I to the CDSA under the heading "Fentanyls, their salts, derivatives, and analogues and salts of derivatives and analogues, includng :". However, the substance does not have the core structure of the fentanyls (shown below) and a review of recent status decisions on other such substances have concluded that a substance must contain the core structure of the fentanyls to be included under item 16 of Schedule I to the CDSA:



where R= ethyl group substituted variously at the 1 and 2 position
R_1= hydrogen, methoxymethyl or carboxylate alkyl ester
R_2= phenyl or substituted phenyl
R_3= alkyl
R_4= hydrogen or alkyl

As such, propionanilide is not considered to fall under the heading of item 16 of Schedule I to the CDSA.

Recommendation: Propionanilide is not included in the Schedules to the CDSA and is not a controlled substance.

Date: May 24, 2011

[1]Garg A., et al (2010). Forced degradation of fentanyl: Identification and analysis of impurities and degradants. Journal of Pharmaceutical and Biomedical Analysis **53:**325-334