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

Substance:  I - O-Isobutyryl Naltrexone
           II - O-Isobutyryl N-Methyl Naltrexone-d3 Iodide

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 substances are derivatives of naltrexone and are included under item 1 of Schedule I to the CDSA.

Prepared by: ___________________________  Date: October 12th, 2011
Vincent Marleau

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 - O-Isobutyryl Naltrexone  
II - O-Isobutyryl N-Methyl Naltrexone-d3 Iodide

**Drug Name Status:**  
I - O-Isobutyryl Naltrexone  
II - O-Isobutyryl N-Methyl Naltrexone-d3 Iodide are the common names.

**Chemical Name:**  
I -(5a)-17-(Cyclopropylmethyl)-4,5-epoxy-14-hydroxy-3-(2-methyl-1-oxopropoxy)-morphinan-6-one  
II - (5a)-17-(Cyclopropylmethyl)-4,5-epoxy-14-hydroxy-17-methyl-3-(2-methyl-1-oxopropoxy)-6-oxo-morphinanium-d3 Iodide

**Other Names:**  
I - Naltrexone 3-isobutyrate; 3-O-Isobutyrylnaltrexone  
II - N/A

**Chemical structure:**

![Chemical Structure I](image1)  
![Chemical Structure II](image2)

**Molecular Formula:**  
I - C\textsubscript{24}H\textsubscript{29}NO\textsubscript{5}; II - C\textsubscript{25}H\textsubscript{29}D\textsubscript{3}INO\textsubscript{5}

**CAS-RN:**  
I - 861238-38-2; II - N/A

**Pharmacological class / Application:** Pharmaceutical-related substances

**International status:**

US: O-Isobutyryl naltrexone and O-isobutyryl N-methyl naltrexone-d3 iodide are not listed on the schedules to the US Controlled Substances Act and are not mentioned anywhere 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: O-Isobutyryl naltrexone and O-isobutyryl N-methyl naltrexone-d3 iodide are not listed specifically in the Schedules to the CDSA. The substances are derivatives of naltrexone, which is excluded specifically from the CDSA and listed as sub-item 1(34.2) in Schedule I in the CDSA. The derivatives of naltrexone, however, are not included under the “but not including” provision and therefore must be included under the heading “Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including:” of item 1 of Schedule I to the CDSA.

**Recommendation:** O-Isobutyryl naltrexone and O-isobutyryl N-methyl naltrexone-d3 iodide are included under Item 1 of Schedule I to the CDSA and are controlled substances.

**Date:** October 12th, 2011