Drug Status Report

Drug: Bromazepam Impurities

A client requested the status of the following bromazepam related substances.

**Chemical Name:**
1. 2-(2-Amino-5-bromobenzoyl)pyridine (EP impurity A) (I)
2. 2-(2-(2-Bromoacetamido)-5-bromobenzoyl)pyridine (II)
3. 2-(2-(2-Chloroacetamido)-5-bromobenzoyl)pyridine (III)
4. 3-Amino-6-bromo-2-hydroxy-4-(2-pyridyl)quinoline (IV)

**Chemical structure:**

I

II

III

IV

**Molecular Formula:**
1. I - C_{12}H_{9}BrN_{2}O
2. II - C_{14}H_{10}BrN_{2}O_{2}
3. III - C_{14}H_{10}BrClN_{2}O_{2}
4. IV - C_{14}H_{10}BrN_{3}O

**Pharmacological class / Application:** pharmaceutical related substance

**International status:**

US: The substances are not listed on the schedules to the US Controlled Substances Act and 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 nor on the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Item 18 of Schedule IV to the CDSA is, “Benzodiazepines, their salts and derivatives”. Bromazepam is subitem 2 of this item. None of substances 1-IV are structurally benzodiazepines so they are not included in item 18.

Recommendation: Substances I, II, III and IV are not included in the schedules to the CDSA and
are not controlled substances.

April 21, 2008