Health Canada Santé Canada

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

Substance: Famprofazone

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 cannot be considered a derivative nor analogue of an amphetamine and therefore is not included in the schedules to the CDSA..

Prepared by: _____ Date: Feb 23rd 2011
Evelyn Soo

Verified by: _____ Date: _____
Marianne Tang

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

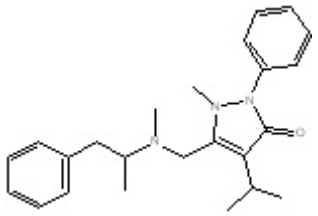
Drug: Famprofazone

Drug Name Status: Famprofazone is the proper (INN) name.

Chemical Name: 1,2-dihydro-1-methyl-4-(1-methylethyl)-5-((methyl(1-methyl-2-phenethyl)amino)methyl)-2-phenyl-3H-pyrazol-3-one

Other Names: 4-Isopropyl-2-methyl-3-(methyl(alpha-methylphenethyl)amino)methyl-1-phenyl-3-pyrazolin-5-one; 3-(N-Methyl-(alpha-methyl-beta-phenyl)-ethyl)-aminomethyl)-4-isopropyl-norantipyrine

Chemical structure:



Molecular Formula: $C_{24}H_{31}N_3O$

Pharmacological class / Application: Analgesic

CAS-RN: 22881-35-2

International status:

US: Famprofazone is not listed specifically in the Schedules to the US *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: Famprofazone is not listed specifically in the CDSA. The substance is the main ingredient in Gewolen, a non-prescription drug sold in Taiwan as an analgesic, and has been shown in the literature to metabolise to methamphetamine and amphetamine[1]. While, the

[1]Chan, KH et al. (2010) Famprofazone use can be misinterpreted as methamphetamine abuse, J. Anal. Toxicol. **34**:347-353.

substance can be considered a precursor to methamphetamine and amphetamine, which are included under item 18 of schedule I and item 1 of schedule III to the CDSA, respectively, famprofazone is not a derivative of either substance. It is also arguable as to whether the substance displays sufficient enough structural similarity to methamphetamine and amphetamine to be considered an analogue of either of the two substances. As such, famprofazone cannot cannot be included under item 18 of Schedule I nor item 1 of Schedule III to the CDSA.

Recommendation: Famprofazone is not is included in the schedules to the CDSA and is not a controlled substance.

Date: 23 February 2011