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

Substance: Mebeverine
Based on the current information available to the Office of Controlled
Substances, it appears that the above substance is:

 Controlled   X
 Not Controlled  □

under the schedules of the Controlled Drugs and Substances Act (CDSA) for the
following reason(s):

• Mebeverine is currently not listed specifically on the CDSA.
  However, Item 1 of Schedule III is, “Amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues including.” As analogue is defined in the CDSA as, “a substance that, in relation to a controlled substance, has a substantially similar chemical structure”, mebeverine must be considered an analogue of amphetamine and 4-methoxyamphetamine - subitems 1(1) and 1(7) respectively, and included in item 1 of Schedule III to the CDSA.

Supporting document attached: Drug Status Report by Mr. LeBelle

Prepared by: __________________________ Date: Sept. 12, 2006
Xiao Peng Feng

Drug Status Report by: Mr. M. LeBelle Date: Sept. 11, 2006

Approved by: __________________________ Date: _________
DIRECTOR, OFFICE OF
CONTROLLED SUBSTANCES
Drug Status Report

**Drug:** Mebeverine

**Drug Name Status:** Mebeverine is the proper name (INN)

**Chemical Name:** 3,4-Dimethoxybenzoic acid 4-[ethyl[2-(4-methoxyphenyl)-1-methylethyl]amino]butyl ester

**Chemical structure:**

![Chemical Structure Image]

**Molecular Formula:** $C_{25}H_{35}NO_{5}$

**Pharmacological class / Application:** anticonvulsant

**International status:**

US: Mebeverine is not listed on the schedules to the CSA and is not mentioned on the DEA website. Amphetamine is listed in Schedule II to the CSA so the analogue provisions of the CSA should apply if a new drug application has not been approved for mebeverine (mebeverine is not USAN). The DEA would have to confirm the status of mebeverine.

United Nations: The 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: Mebeverine is currently not listed specifically on the CDSA. However, Item 1 of Schedule III is, “Amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues including.” As analogue is defined in the CDSA as, “a substance that, in relation to a controlled substance, has a substantially similar chemical structure”, mebeverine must be considered an analogue of amphetamine and 4-methoxyamphetamine - subitems 1(1) and 1(7) respectively; (structures below).
Recommendation: Mebeverine is included in item 1 of Schedule III to the CDSA and is a controlled substance.

September 11, 2006