



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: Xiao Peng Feng Date: Sept. 12, 2006

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

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

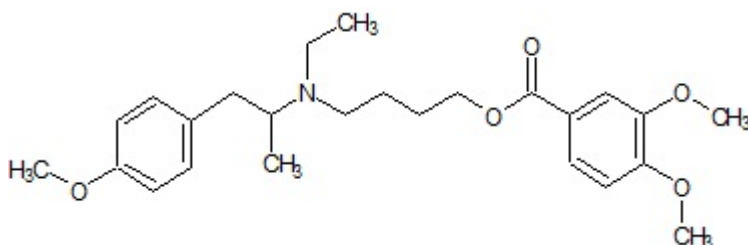
Drug Status Report

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:



Molecular Formula: C₂₅H₃₅NO₅

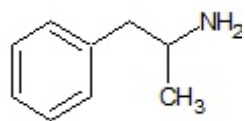
Pharmacological class / Application: anticonvulsant

International status:

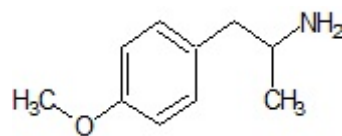
US: Mebeverine is not listed on the schedules to the CSA and is not mentioned on the DEA website. Amphetamine is listed in Schedule II to the CSA so the analogue provisions of the CSA should apply if a new drug application has not been approved for mebeverine (mebeverine is not USAN). The DEA would have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



Amphetamine



4-Methoxyamphetamine

Recommendation: Mebeverine is included in item 1 of Schedule III to the CDSA and is a controlled substance.

September 11, 2006

