Health Canada
Santé Canada

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

Substance: SCH57871

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

Controlled	☐
Not Controlled	X

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

- SCH57871 is not structurally similar to any of those listed in the CDSA.

Prepared by: _____ Date: _____
Benoit P Seguin

Verified by: _____ Date: _____
Mark Kozlowski

Approved by: _____ Date: _____
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Bruno Lafontaine, OCS

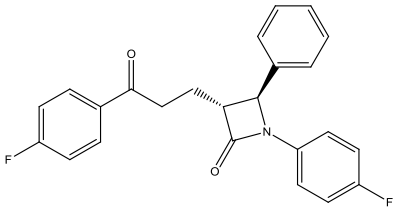
Drug Status Report

Drug: SCH57871

Drug Name Status: SCH57871 is the common name.

Chemical Name: (3R,4S)-1-(4-fluorophenyl)-3-[3-oxo-3-(4-fluorophenyl)propyl]-4-(4-hydroxyphenyl)-2-azetidinone

Chemical structure:



Molecular Formula: $C_{24}H_{19}F_2NO_3$

Pharmacological class / Application: Pharmaceutical-related impurity

CAS-RN: N/A

International status:

US: SCH57871 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: SCH57871 is not listed in the Schedules to the CDSA. The substance is an impurity of ezetimibe, a drug that is used for the reduction of cholesterol and blood lipoproteins[i]. Ezetimibe is currently regulated under the *Food and Drugs Regulations* as a Schedule F drug. SCH57871 is not structurally similar to any of the substances listed in the CDSA.

Recommendation: SCH57871 is not included in the schedules to the CDSA and is not a controlled substance.

Date: November 15th, 2012.

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[i]Patrick, J.E. et al. (2002) Disposition of the Selective Cholesterol Absorption Inhibitor Ezetimibe in Healthy Male Subjects, Drug Met Disp, **30:**430-437.