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

Substance: Pirfenidone

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):

- The substance does not display any structural similarity to those included in the schedules to the CDSA.

Prepared by: ______________________________________ Date: _______________

Zack Li

Verified by: ______________________________________ Date: _______________

Mark Kozlowski

Approved by: ______________________________________ Date: _______________

DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Robin Kilmury, CBSA
Drug Status Report

**Drug:** Pirfenidone

**Drug Name Status:** Pirfenidone is the INN name.

**Chemical Name:** 2(1H)-Pyridinone, 5-methyl-1-phenyl-

**Other Names:** 2(1H)-Pyridone, 5-methyl-1-phenyl-; Pirespa; Esbriet; Deskar

**Chemical structure:**

![Chemical structure diagram]

**Molecular Formula:** $\text{C}_{12}\text{H}_{11}\text{NO}$  \hspace{1cm} **CAS-RN:** 53179-13-8

**Pharmacological class / Application:** Pharmaceutical-related substance

**International status:**

US: Pirfenidone 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: Pirfenidone is not listed in the CDSA. The substance is currently undergoing clinical trials in the United States as a treatment for idiopathic pulmonary fibrosis. Pirfenidone does not display any structural similarities to the substances included in the CDSA and therefore cannot be included under the Schedules to the CDSA.

**Recommendation:** Pirfenidone is not included under the Schedules to the CDSA and is not a controlled substance.

**Date:** July 23rd, 2012.

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