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

Substance: ACE-031

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 is not listed in the Schedules to the CDSA and is not similar to any
  of the substances included in the CDSA.

Prepared by: ____________________________  Date: July 11, 2011
           Zack Li

Verified by: ____________________________  Date: __________
           Mark Kozlowski

Approved by: ____________________________  Date: __________
           DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Brian Yakiwchuk, RAPB
Drug Status Report

**Drug:** ACE-031

**Drug Name Status:** ACE-031 is the common name.

**Chemical Name:** ActRIIB-IgG1

**Other Names:** Soluble Activin Type IIB Receptor

**CAS RN:** Unknown

**Pharmacological class / Application:** Protein

**International status:**

US: ACE-031 is not currently listed on the schedules to the US Controlled Substances Act and is not mentioned 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: ACE-031 is a fusion protein derived from human activin receptor type IIB and is undergoing testing as a treatment for Muscular Dystrophy\(^1\). The substance is not listed in the CDSA and is not structurally similar to any of the substances included in the Schedules to the CDSA. Although it has been reported that ACE-031 is used for bodybuilding purposes, it is not an anabolic steroid and therefore cannot be included under Item 23 of Schedule IV to the CDSA.

**Recommendation:** ACE-031 is not included in the schedules to the CDSA and is not a controlled substance.

**Date:** July 11, 2011

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