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

Substance:  Zearalenol (alpha and beta)

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):

•  Neither alpha-zearalenol nor beta-zearalenol are on the schedules
to the CDSA.
•  A structurally related substance, zeranol, is listed as item 24 of
  Schedule IV. However, the listing of zeranol is not extended
  beyond the listed substance.

Supporting document(s) attached: X

Prepared by:  _______________________________  Date:  2005-07-06
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Approved by:  _______________________________  Date:  __________
**Drug:** Zearalenol (alpha and beta)

**Drug Name Status:** alpha-Zearalenol and beta-zearalenol are common names.

**Chemical Name:** The alpha isomer: (3S,7R,11E)- 3,4,5,6,7,8,9,10-octahydro-7,14,16-trihydroxy-3-methyl-1H-2-Benzoxacyclotetradecin-1-one
The beta isomer: (3S,7S,11E)- 3,4,5,6,7,8,9,10-octahydro-7,14,16-trihydroxy-3-methyl-1H-2-Benzoxacyclotetradecin-1-one,

**Chemical structure:**

![Chemical Structure](image)

The structure is applicable to both alpha-zearalenol and beta-zearalenol in that the hydroxyl is alpha for the alpha isomer and beta for the beta isomer.

**Molecular Formula:** $C_{18}H_{24}O_5$

**Pharmacological class / Application:** metabolite of mycotoxin zearalenone.

**International status:**

US: The drug is not currently listed specifically on the US Controlled Substances Act and is not mentioned on the DEA website.

United Nations: The drug is not listed on the Yellow List - List of Narcotic Drugs under International Control. The drug is not listed on the Green List - List of Psychotropic Substances under International Control

Canadian Status: Neither alpha-Zearalenol nor beta-zearalenol are on the schedules to the CDSA. A structurally related substance, zeranol, is listed as item 24 of Schedule IV. However, the listing of zeranol is not extended beyond the listed substance.

**Recommendation:** alpha-Zearalenol; beta-zearalenol are not included in the schedules to the CDSA and neither is a controlled substance.

July 5, 2005