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

Substance:  Gestrinone

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

<table>
<thead>
<tr>
<th>Controlled</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Controlled</td>
<td>□</td>
</tr>
</tbody>
</table>

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

• Gestrinone is a steroid that is not listed in the schedules to the
  CDSA. Its commercial application as a birth control agent is
  based on its progestational properties. It is closely related to
tetrahydrogestrinone which was declared to be controlled
substance in July, 2006 due to its anabolic activity.

  No published primary references to the anabolic activity of
gestrinone through PubMed. However, there appears to be world
wide recognition that gestrinone has anabolic activity. Gestrinone
is listed as an anabolic androgenic steroid by WADA and has
been labelled an anabolic steroid by the FDA.

Supporting document attached: Drug Status Report by Mr. LeBelle

Prepared by: ____________________________ Date: Sept. 28, 2006

Xiao Peng Feng

Drug Status Report by:  Mr. M. LeBelle       Date:  September 27, 2006

Approved by: ____________________________ Date: __________

DIRECTOR, OFFICE OF
CONTROLLED SUBSTANCES
Drug Status Report

Drug: Gestrinone

Drug Name Status: Gestrinone is the proper name (INN and USAN).

Chemical Name:
13-Ethyl-17-hydroxy-18,19-dinor-17alpha-pregna-4,9,11-trien-20-yn-3-one

Other Names: 13-Ethyl-17-alpha-ethinyl-17-hydroxygon-4,9,11-trien-3-one

Chemical structure:

![Chemical Structure Image]

Molecular Formula: $\text{C}_{21}\text{H}_{24}\text{O}_2$

Pharmacological class / Application: steroid

International status:

US: Gestrinone is not listed on the schedules to the US Controlled Substances Act and is not mentioned on the DEA website.

United Nations: The chemical 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: Gestrinone is a steroid that is not listed in the schedules to the CDSA. Its commercial application as a birth control agent is based on its progestational properties. It is closely related to tetrahydrogestrinone which was declared to be controlled substance in July, 2006 due to its anabolic activity.

No published primary references to the anabolic activity of gestrinone through PubMed. However, there appears to be world wide recognition that gestrinone has anabolic activity. Gestrinone is listed as an anabolic androgenic steroid by
WADA and has been labelled an anabolic steroid by the FDA\textsuperscript{1}.

Recommendation: As gestrinone has anabolic activity, it is an anabolic steroid included in item 23 of Schedule IV and is a controlled substance.

September 27, 2006

\textsuperscript{1} http://www.fda.gov/fdac/departs/2004/104_upd.html