



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:

Controlled X
Not Controlled [ ]

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: Xiao Peng Feng Date: Sept. 28, 2006

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

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date: \_\_\_\_\_

## Drug Status Report

**Drug:** Gestrinone

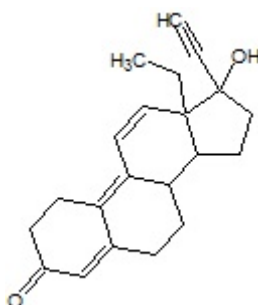
**Drug Name Status:** Gestrinone is the proper name (INN and USAN).

**Chemical Name:**

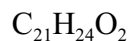
13-Ethyl-17-hydroxy-18,19-dinor-17alpha-pregna-4,9,11-trien-20-yn-3-one

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

**Chemical structure:**



**Molecular Formula:**



**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<sup>1</sup>.

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

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<sup>1</sup> [http://www.fda.gov/fdac/departs/2004/104\\_upd.html](http://www.fda.gov/fdac/departs/2004/104_upd.html)