

Section 12 Notice Additional Information Required to Fulfill the Terms and Conditions for Conditional Registration

Product Name: **CYDIA POMONELLA GRANULOVIRUS**
Registration Number: **26532**
Application Number: **2005-0935**
PMRA #: **1490470**

During the conditional registration period which has been granted to December 31, 2008, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by **September 1st, 2008** and should indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

PART M2 PRODUCT CHARACTERIZATION AND ANALYSIS

DACO: **M2.5**
Title: **Binomial name**

Deficiencies: A strain designation for the active ingredient was not specified.

Required data: **A strain designation is required**

DACO: **M2.7.1**
Title: **Origine, derivation and identification of MPCA**

Deficiencies: a) The applicant previously submitted a copy of a gel electrophoresis figure showing DNA restriction enzyme fragments of the *Cydia pomonella* granulovirus (CpGV) active ingredient. While the gel figure does provide a restriction pattern that may be used for identification purposes, it does not contain any other CpGVs for comparison, nor a DNA ladder with a marker band larger than 12,216 kb (1kb ladder) for better estimation of the larger DNA fragments.

b) Data to validate equivalence of the MPCA to that manufactured at the original source (i.e., site) were not submitted.

- Required data:**
- a) **The applicant must repeat this analysis and include a high molecular weight marker, in addition to the 1 kb ladder, as well as any other CpGV strains that are available. The electrophoresis gel should be run for a longer time to provide better separation of the DNA fragments, which will provide a more effective means of differentiation.**
 - b) **Data to demonstrate equivalence is required. Such data can include but is not limited to a comparison of the host specificity of the two CpGV preparations against targeted and other potentially susceptible insect host species , a comparison of microscopic morphological features, and restriction enzyme analysis of DNA or any other suitable molecular technique (e. g., gene-specific probes) that can be used to differentiate strains of CpGV.**

DACO: M2.8

Title: Manufacturing methods and quality assurance

- Deficiencies:**
- a) A detailed description of the methods used for preservation and maintenance of the production strain was not submitted.
 - b) A detailed description of the manufacturing methods were not submitted.
 - c) The method for determining occlusion body counts and the corresponding data were not provided.

- Required data:**
- a) Submit a detailed description of the methods used for preservation and maintenance of the production strain.
 - b) Submit a detailed description of the manufacturing methods.
 - c) Submit the method used for determining the occlusion body count along with corresponding raw data, preferably for batch Cp-VIII-10/01.03.03.