

**Section 12 Notice**

**Additional Information Required to Fulfill the Terms and Conditions for Conditional Registration**

***Product Name:*** ***NOLO BB CONCENTRATE***  
***Registration Number:*** ***29196***  
***Application Number:*** ***2007-0260***  
***PMRA # :*** ***1690038***

During the conditional registration period which has been granted to December 31, 2010, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by September 30, 2010 and should indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

**PART 0 INDEX**

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**DACO:** 0  
**Title:** Index

**Details:** **Please submit an electronic index of the data package submitted in response to this letter. Please refer to Regulatory Directive 2006-05, *Requirements for Submitting Data Index, Documents and Forms*, for additional information.**

**PART 2 CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF A TECHNICAL GRADE OF ACTIVE INGREDIENT (TGAI) OR AN INTEGRATED SYSTEM PRODUCT**

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**DACO:** 2.8  
**Title:** Manufacturing Methods and Quality Assurance

**Details:**

- **In the submitted document entitled “Manufacturing Process” it has been stated that, “If it appears microscopically that there are higher than average number of bacteria in any colony, a specimen is taken and sent to the local hospital microbiology laboratory for identification and sensitivities.” It is not clear what is meant by “higher than average number”. Please provide the number in terms of CFUs.**
- **In the same document it has been stated that “We could clean the concentrate further by washing the spores first in a mild chlorine solution and then again in clean distilled if necessary.” Please clarify:**
  - **at what level of bacterial contamination is the mild chlorine solution being used?**
  - **at what concentration and rate is the chlorine solution being used?**

**DACO:** 2.10.2  
**Title:** Analysis for Microbial Contaminants

**Details:**

**The applicant is requested to provide following information:**

- **five certificates of quantitative analysis on microbial contaminants, i.e., bacterial and fungal contaminants using the most recently manufactured batches of the TGAI.**
- **acceptable limits for each of the microbial contaminants.**
- **details of the methods used for the bacterial and fungal contaminant analysis.**
- **as per PMRA requirements, every batch of TGAI must be screened for microbial contaminants, including the steps or measures taken if the batches contain microbial contaminants beyond their acceptable limits.**