

Appendix 1

Review of Amendment 6 - Responses to Information Request Dated 08 April 2013 for Issues that could affect Filing

Recommendation: I reviewed the response in Amendment 6 and found them to be acceptable. I do not have any further comments or questions related to this amendment.

Review

The FDA questions are in **bold** font and Bioclon's responses are in *italicized* font.

Module 1 Contents

1. Please note that the (b) (4) facility is required to have its own FEI number. If you have not already applied for one, please do so now. If you have already applied for one, please provide the date you applied for the FEI number.

Instituto Bioclon Response:

Instituto Bioclon applied for a DUNS number which is required for the registration of an Establishment. An application for a FEI number for (b) (4) facility will be done once the DUNS number is obtained.

Reviewer Comment: This response is acceptable.
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Module 3 Contents: Drug Product Equipment

2. Please provide a description of the depyrogenation tunnel and the filling line used in the (b) (4) facility.

Instituto Bioclon Response:

A description of the depyrogenation tunnel and the filling line used in the (b) (4) facility is locations is provided in Module 3.2.A.1 Facility and Equipment-Equipment-(b) (4) Facility: summary-for-filling-equipment and summary-for-depyro-equipment.

Reviewer Comment: This response is acceptable. The review of this information is part of the Primary Review memo and is located within the appropriate sections of the review memo. Any additional questions will be asked during the Primary Review, if necessary.

3. Please provide summaries of the equipment qualification for the depyrogenation tunnel and the filling line used in the (b) (4) facility. (b) (5), (b) (7)(E)

Instituto Bioclon Response:

Summaries of the equipment qualification for the depyrogenation tunnel and the filling line used in the (b) (4) facility is provided in Module 3.2.A.1 Facility and Equipment-Equipment-(b) (4) Facility: summary-for-filling-equipment and summary-for-depyro-equipment.

Reviewer Comment: This response is acceptable. The review of this information is part of the Primary Review memo and is located within the appropriate sections of the review memo. Any additional questions will be asked during the Primary Review, if necessary.

4. The brief, high-level description of the filling process seemed to indicate that some sort of (b) (4) (b) (4) Please provide information on the (b) (4) Please provide a description of the equipment along with a summary of the executed performance qualification.

Instituto Bioclon Response:

Information on the (b) (4) (b) (4) along with a summary of the executed performance qualification is provided in Module 3.2.A.1 Facility and Equipment-Equipment-(b) (4) Facility: summary-for-the-(b) (4) .

Reviewer Comment: This response is acceptable. The review of this information is part of the Primary Review memo and is located within the appropriate sections of the review memo. Any additional questions will be asked during the Primary Review, if necessary.