



Our Reference: BL 125488/0

Instituto Bioclon, S.A. de C.V.
Attention: Ms. Jennifer Spinella
April 8, 2013
Sent by facsimile

Dear Ms. Spinella:

We are reviewing your March 16, 2013 biologics license application (BLA) for Crotalidae (pit viper) Immune F(ab')₂ (Equine) Injection. We are providing the following comments and request for additional information to continue our review:

The following issues identified may affect filing of the application:

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.

**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.
3. Please provide summaries of the equipment qualification for the depyrogenation tunnel and the filling line used in the (b) (4) facility. A more complete review of the equipment qualification can be performed on inspection.
4. The brief, high-level description of the filling process seemed to indicate that some sort of (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.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by April 22, 2013 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is March 18, 2014.

Please send an email message acknowledging receipt of this request.

If you have any questions, please contact me at (301) 827-9167.

Sincerely,

Edward Thompson
Regulatory Project Manager
FDA/CBER/OBRR/DBA/RPMB