

From: Wood, Lorraine
Sent: Thursday, March 23, 2017 10:42 AM
To: MaryAnn Lamb <MaryAnn.Lamb@bpl-us.com>
Subject: Information Request for BLA 125644: Sterility/(b) (4)
Importance: High

Dear Dr. Lamb,

We are reviewing your submission for BLA 125644 Human Albumin Solution (HAS) 5% and 25%; we request the following information to continue our review:

Sterility

1. In section 3.2.P.5.1, 'Specification', please change the acceptance criterion from 'pass' to 'no growth detected/observed'.
2. In section 3.2.P.5.3, 'Validation of Analytical Procedures', please provide concentration (i.e., 5% and 25%) of batches (i.e., (b) (4)) used in sterility test qualification study.
3. Please provide complete Bacteriostasis and Fungistasis qualification report including type of media, conformance lot numbers, incubation conditions and duration, to show suitability of sterility test for the intended purpose.

(b) (4) Endotoxin Test ((b) (4))

1. Please provide (b) (4) endotoxin qualification report for Human Albumin Solution 5% and 25% showing these drug product matrixes are suitable for testing using your (b) (4) method. The report should include maximum valid dilution, lot numbers of product tested, positive product control % recoveries and selected product testing dilution.
2. Regarding (b) (4) results in section 3.2.P.5.3, the test results for (b) (4) testing were listed as 0 IU/mL. The test results should be presented relative to the specification (i.e., less than or the measurable value, taking into account calculations based on the test dilution used).

Please respond to this request to this request by Thursday April 6, 2017.

Thank you

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