

Rana, Pratibha

From: Rana, Pratibha
Sent: Thursday, November 29, 2012 11:11 AM
To: 'Gary Ingenito'
Subject: STN 125389/0 Information Request

Gary,

Previously Biotest had submitted the following CE for EA:

1.12.14 Environmental Analysis

Under the provisions of 21 CFR 25.31 (j), action on a Biologics License Application is categorically excluded and, therefore, ordinarily does not require the preparation of an Environmental Assessment or an EIS. Biotest claims a categorical exclusion to the Environmental Assessment requirements in accordance with 21 CFR 25.31(e) for Biotest-IGIV. To the best knowledge of Biotest, the applicant is not aware of the existence of any extraordinary circumstances that would require the preparation of an Environmental Assessment. Also, Biotest does not have any information to indicate that Biotest-IGIV and products associated with its manufacture may be toxic to organisms in the environment at the expected levels of production.

Please state that Biotest requests this in accordance with 21 CFR 25.31(c), not -(e). Please resubmit this section under -(c).

Please let me know if you have any questions.

Thank You.

Pratibha Rana
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