

Record of Telephone Conversation, December 7, 2011 - Flublok

- Submission Type: BLA Submission ID: 125285/0 Office: OVRR
Product:
Influenza Vaccine
Applicant:
Protein Sciences Corporation
Telecon Date/Time: 07-Dec-2011 03:06 PM Initiated by FDA? Yes
Telephone Number: Communication conveyed via e-mail
Communication Category(ies):
1. Advice
2. Information Request
Author: TIMOTHY FRITZ
Telecon Summary:
Process and fill validation comments and requests.
FDA Participants: Timothy Fritz
Non-FDA Participants: Penny Post
Trans-BLA Group: No
Related STNs: None
Related PMCs: None
Telecon Body:
From: Fritz, Timothy
Sent: Wednesday, December 07, 2011 3:06 PM
To: Penny Post (penny.post@proteinsciences.com)
Subject: CBER Process and Fill Validation Comments

Importance: High

Attachments: CBER Process and Fill validation comments.doc
Dear Dr. Post-

CBER's review of Protein Sciences Corporation's September 16, 2011 submission (Amendment 47) to STN 125285 is ongoing. We have the following comments on your responses to our May 27, 2011 Information Request and the information provided in your November 21, 2011 submission (Amendment 49):

CBER Comment 1a.

b. You have provided data in various submissions to support column re-use for H1, H3 and B rHA downstream process steps.

Please summarize acceptable running conditions for all strains by providing a tabular listing of the number of column runs and the number of repackings as well as column

acceptance criteria for all subtypes. Please include consistent void volume for each column as an acceptance criterion and please provide the current specified number of re-uses for each column.

It is unclear if you can achieve acceptable separation at flow rates of –b(4)----- and –b(4)----for the –b(4)----- columns, respectively. Please comment.

To determine whether you have established adequate b(4) acceptance criteria please provide baseline b(4) levels from the –b(4)----- columns prior to their use in production.

CBER Comment 3c.

The monovalent bulk specifications as submitted November 21, 2011 are acceptable.

The specifications for drug product at release as submitted November 21, 2011 are acceptable. The potency (SRID) specification at release –b(4)----- for each strain) provides confidence that the product will maintain the labeled dose (45 µg/dose) up to the expiry date. In the footnote, it is explained that –b(4)-----
----- Please note that since the labeled dose of Flublok is 45 µg/dose, the lowest concentration acceptable for distributed product is –b(4)----- to accommodate assay variability when results of –b(4)- vials are averaged. Please confirm that this is the number of vials proposed for release and stability testing with % RSD specifications as mentioned above.

If PSC decides to test –b(4)-----, respectively, the acceptable RSD will be –b(4)----- with the lowest concentration acceptable for distributed product at –b(4)----- to accommodate assay variability when the results of –b(4)---- vials are averaged.

CBER Comment 7b.

The addition of –b(4)----- in H3 preparations is acceptable; however there is some concern that this may reduce the sensitivity of –b(4)-----
----- tests. Please provide data for the –b(4)----- and –b(4)-----
----- tests to demonstrate equivalence of assay sensitivity in the presence and absence of the maximum amount of –b(4)----- . Please also provide the sample dilution for H3 samples tested for –b(4)----- in 2010 (or prior to addition of –b(4)----- to the monovalent bulk) and 2011, and data for the spike controls for all H3 lots manufactured in 2010 and 2011.

As indicated, CBER's review is ongoing and CBER will provide comments regarding PSC's response to Comment 4 of CBER's May 27, 2011 Information Request as soon as possible.

If you have any questions, please contact the Regulatory Project Manager, Dr. Timothy Fritz, at 301-796-2640.

Thank you.

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