



Our STN: BL 125384/0

Kedrion, S.p.A.
Attention: Mr. Urs E. Aeberli
FFF Enterprises, Inc.
May 16, 2011
Sent by email: uaeberli@fffenterprises.com

Dear Mr. Aeberli:

We are reviewing your August 2, 2010 submission to your original BLA for Albumin (Human). We determined that the following information is necessary to continue our review

Comments on Lot Release Protocol template for 125324/0

1. Please remove the Mean Reduction Factor numbers of REO, PPV, and HAV for the step of Fractionation of Effluent IV-1 to Effluent IV-4, and recalculate the Overall Reduction Factor accordingly. Please referred to the attached table.
2. Please add footnotes under the table for the abbreviations used in the table (i.e. viruses).

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission. If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

Please submit your response to this information request as an amendment to this file by May 18, 2011. 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. The action due date for this file is June 3, 2011.

If you have any questions, please contact me at (301) 827-3927.

Sincerely,

Crystal Allard
Regulatory Project Manager
FDA/CBER/OBRR/DBA/RPMB