DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
1401 Rockville P ke
Rockville, MD 20852-1448

Our STN: BL 125384/0

Kedrion, S.p.A.
Attention: Mr. Urs E. Aeberli
FFF Enterprises, Inc.
April 11, 2011
Sent by email: uaeberli@fffenterprises.com

Dear Me. 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

Page All

1. Remove "BL" from "cc:" line at the top of each page.
2. License name of the product is not the trade name, the name in those fields should state: "Albumin (Human)". This is the name the product will be released under.

Page 1

1. Please remove "Other: N.A" and "Recommended Reconstitution Volume: N.A.", since that information is not needed for this product.

Page 2

1. Remove Bulk Sterility test from page two.

2. For the Final Container Sterility data, please list all test dates for each item.

3. For the General Safety data, please list all test dates and route of inoculation for each animal. For clarity in reading each test result should be in its own distinct row.

Page 4

1. Remove Gel Clot test, since it is not being used.

Page 6

Number of pages (including cover sheet) _

1. Normally if the protocol is going to list the units for a test once, it is usually listed with the limit/specification and not the test description.

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 16, 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

Number of pages (including cover sheet) _