DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Our STN: BL 125384/0

Kedrion, S.p.A.
Attention: Mr. Urs E. Aeberli
FFF Enterprises, Inc.
April 28, 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 related to the lot release protocols is necessary to continue our review:

1. A template was not submitted for review, the protocol for lot --(b)(4)-- was reviewed for the information that will be provided.
2. Delete sections of the template that are not applicable to the specific product, for example Antibody Potency, Diphtheria Potency and the Mycoplasma test report on pages 7 and 8.
3. In the ----------(b)(4)---------- Reporting Form on page 3 the STD Run time should be in seconds, not cycles.
4. On page 5, Sample Rabbit Pyrogen Reporting form the Dose should be in ml, the ml given to each rabbit. The header of that column could read :

Dose (ml)

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 5, 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) _