**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

1. Please include the 0 – 28 day age group in your study population or provide a rationale for not including this age group in your study.
2. Please change the draft protocol terms primary and secondary "endpoints" to primary and secondary safety parameters since there will be no formal hypothesis testing for efficacy. All primary safety parameters should include standardized criteria as well a scoring system to rank their severity and seriousness.
3. Please use a stratified randomization approach based on type of surgery, e.g., cardiac, orthopedic, etc.
4. Please define the duration required before hemodynamic stabilization can be declared. In addition, please indicate how return of hemodynamic instability within the 3 day treatment period following declaration of hemodynamic stabilization will be addressed in terms of the primary safety parameter.
5. Please clarify the Dosing & Administration section of the protocol with respect to whether the test product will be titrated to (a) age-adjusted hemodynamic parameters (page 27, protocol) and/or (b) a serum albumin level of 3.5 g/dL for the whole treatment duration (page 26, protocol).
6. Please justify the target serum albumin level of 3.5 g/dL in the Dosing & Administration section.
7. Please add prespecified RBC transfusion trigger guidelines/algorithm for transfusion of FFP and platelets as this may impact the safety profile of the fluid resuscitation regimen.
8. Please clarify what is meant by the phrase "if available" as part of the statement that "data will be captured at various time points, if available".
9. Please clarify the time point dry weight will be captured.
10. Please submit the final statistical analysis plan and informed consent document with your revised draft protocol.

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 11, 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) _