From: Allard, Crystal
Sent: Wednesday, January 19, 2011 4:44 PM
To: 'Urs Aeberli'
Subject: Kedrion Albumin BLA lot release and sample submission 125384/0
Signed By: CRYSTAL.ALLARD@FDA.HHS.GOV

Dear Mr. Aeberli,

We are reviewing your August 2, 2010 submission to your original BLA for Albumin (Human) and have the following information regarding lot release and submission of samples. We are requesting you send 3-5 vials from each conformance lot.

All biological products (including those for release action, in support of licensing actions or a complaint sample) should be addressed as follows:

Shipped by Courier Service:
Sample Custodian (ATTN: HFM-672)
Center for Biologics Evaluation and Research
Bldg: NLRC-B, Room: 113
5516 Nicholson Lane
Kensington, Maryland 20895

The reason for the sample submission should appear on the external shipping label and also on the packing slip if one is used. Examples of this include: product release sample(s); inspection sample(s); in support of license action (include CBER assigned STN/Supplement Number);
complaint sample(s); or research sample(s).

If commercial carriers are used, manufacturers should arrange for prepaid delivery from Washington area airports directly to the CBER. Commercial carriers must be instructed to deliver between the hours of 8:00 a.m. and 3:30 p.m., weekdays only (excluding federal holidays). Packages should include holding instructions to carrier if delivery cannot
be made during these hours.

All product samples submitted to the CBER for release or for license actions must have an identifying label affixed to each individual sample container. The container label should include, at a minimum, the proper name for the product, the lot number and the manufacturer’s name,
address, and license number. Final containers of products which cannot be labeled individually such as capillary tubes, multiple puncture devices, etc. need not bear an individual identifying label provided the container(s) is (are) placed in a package to which a label is affixed. Because of the risk of not being able to identify correctly the samples, the practice of shipping multiple unlabeled samples in plastic bags or other temporary package forms with only a single unaffixed label is not acceptable.

The action due date for this file is June 3, 2011.

Please contact the Product Release Branch with any questions or concerns.

Thanks!

Crystal Allard, RAC
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