From: CBER Complicheck
Sent: Friday, June 03, 2011 2:38 PM
To: Peters, Lori
Subject: RE: Request for Compliance Check ----------(b)(4)---------- under BLA 125384/0, Action Due 6/3/11

Firm:
Applicant: Kedrion, S.p.A.
Address: Loc. Ai Conti, 55051 Castelvecchio Pascoli, Barga (Lucca), Italy (Headquarters address, production address is listed below.)
US License Number (if any): Not official
FEI#: 3008919567

Kedrion Biopharmaceutical, S.p.A
Via Provinciale
Bolognana, Gallicano (Lucca)
Italy 55027
FEI# 3008919567

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STN #: BLA 125384/0

Summary: Kedrion Biopharmaceuticals, S.p.A. is seeking licensure for their 25% Human Albumin Solution (intravenous). This will be Kedrion's first licensed product sold in the US. Kedrion was inspected by DMPQ and OBRR in February 2011 and it was the first ever inspection of the facility. Kedrion purchases the albumin paste, an intermediate in the production of the final product, ----------(b)(4)----------.

A Pre-approval inspection (PAI) of Kedrion Biopharmaceuticals, S.p.A. was conducted February 23-25, 28 and March 1-2, 2011 and classified as Voluntary Action Indicated (VAI). The inspection was endorsed on May 31, 2011 and final closeout memo is dated May 31, 2011. Therefore, the Office of Compliance and Biologics Quality, Division of Case Management does not object to the approval of this supplement. Therefore, the Office of Compliance and Biologics Quality, Division of Case Management does not object to the approval of this supplement.

Shannon Aldrich, CSO
CBER/OCBQ/DCM/HFM-610

From: Peters, Lori
Sent: Friday, June 03, 2011 11:53 AM
To: CBER Complicheck
Cc: Renshaw, Carolyn; Trout, Deborah; Norwood, Laurie; Eltermann, John; McGuire, Jeffrey

Subject: Request for Compliance Check ------(b)(4)-------- under BLA 125384/0, Action Due 6/3/11

Hello -
DMPQ is requesting a second compliance check for BLA STN 125384/0 - ----------(b)(4)---------- of the albumin paste intermediate to Kedrion. Kedrion is seeking licensure and approval for the manufacture of the albumin paste into the final product of the 25% Human Albumin Solution.

ESTABLISHMENT EVALUATION REQUEST

Date: June 3, 2011
Request Type: Original
Reviewer's Name, Division, Mail Code, Phone#:
Lori Peters, DMPQ, HFM-676, 301-827-1338
Application Number or Supplement Number and Type:
BLA; 125384/0
Due Date: June 3, 2011

Brief Description of the application or detailed summary of the supplement, including product's and establishment's (Indicate if the supplement represents an improvement or change intended to help the applicant or location achieve compliance):
Kedrion Biopharmaceuticals, S.p.A. is seeking licensure for their 25% Human Albumin Solution (intravenous). This will be Kedrion's first licensed product sold in the US. Kedrion was inspected by DMPQ and OBRR in February 2011 and it was the first ever inspection of the facility. Kedrion purchases the albumin paste, an intermediate in the production of the final product, ----------(b)(4)----------.

Applicant: Kedrion, S.p.A.
Address: Loc. Ai Conti, 55051 Castelvecchio Pascoli, Barga (Lucca), Italy (Headquarters address, production address is listed below.)
US License Number (if any): Not official
FEI#: 3008919567

The address of the manufacturing facility where the Albumin is manufactured is the following: Via Provinciale; Bolognana, Gallicano (Lucca); Italy 55027

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Lori Peters

Consumer Safety Officer
FDA/CBER/OCBQ/DMPQ
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