



DEPARTMENT OF HEALTH & HUMAN SERVICES

US Food & Drug Administration
Center for Biologics Evaluation & Research
Office of Compliance & Biologics Quality
Division of Manufacturing & Product Quality

MEMORANDUM – Environmental Assessment Review

To: Administrative BLA File: STN 125384/0

From: Lori Peters, Consumer Safety Officer, CBER/OCBQ/DMPQ/MRB I

Through: Carolyn Renshaw, Branch Chief, CBER/OCBQ/DMPQ/MRB I

Cc: Yiping Jia, Chair, CBER/OBRR/DH/LBVB
Crystal Allard, RPM, CBER/OBRR
Deborah Trout, Team Lead, CBER/OCBQ/DMPQ/B1
Sean Byrd, Reviewer, CBER/OCBQ/DMPQ/B1

Applicant: Kedrion Biopharmaceuticals, S.p.A.

Subject: Review of request for categorical exclusion from preparation of an Environmental Assessment under 21 CFR 25.31 (c) for the Kedrion Biopharmaceuticals, S.p.A. BLA STN 125384 for 25% Human Albumin Solution, for the indications of Hypovolemia, Hypoalbuminemia, Prevention of Central Volume Depletion, Ovarian Hyperstimulation Syndrome, Adult Respiratory Distress Syndrome, Burns, Hemodialysis, and Cardiopulmonary Bypass Procedure

ADD: June 3, 2011

Recommended Action:

Based on review of the information provided, I conclude that the request for categorical exclusion from preparation of an Environmental Assessment under 21 CFR 25.31 (c) is justified.

Summary:

Kedrion Biopharmaceuticals, S.p.A. has requested that the requirement for an Environmental Assessment be waived in the subject BLA. The claim for categorical exclusion can be found in Module 1 Administrative Information, Section 1.12.14 Environmental Impact Analysis Statement, of the BLA submission (STN 125384/0). Under 21 CFR 25.31 (c), the requirement for an environmental impact assessment is categorically waived for an application to market a biologic product if the substances associated with that product occur naturally in the environment and the action of the product does not significantly alter the concentration or distribution of those substances, their metabolites, or degradation products in the environment. Kedrion Biopharmaceuticals, S.p.A. confirmed that these conditions apply to their subject biologic. The biologic product is protein-based, is composed of naturally occurring substances, and appears to

meet the applicable exclusion criteria under 21 CFR 25.31 (c); there is no information indicating that extraordinary circumstances exist. I find this claim for categorical exclusion to be justified.

Lori Peters, DMPQ Consumer Safety Officer	Date
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Concurrence:

John A. Eltermann, Jr., R.Ph., M.S. Director Division of Manufacturing and Product Quality	Date
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