



Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Biologics Evaluation and Research

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**To:** STN: 125335.0

**From:** Pei Zhang, MD, Division of Hematology (DH), OBRR, HFM-345

**Through:** Dorothy Scott, M.D., LPD Chief, DH, HFM-345  
Robert Fisher, Ph.D., LPD Chief, DH, HFM-345

**CC:** Debbie Cordaro RPM, HFM-370

**Applicant:** Rare Disease Therapeutics. Inc.

**Product:** Centruroides (Scorpion) Immune F(ab)<sub>2</sub> Intravenous (Equine)  
Trade name: Anascorp<sup>®</sup>

**Subject:** Final Review

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**Recommendation**

Approval

**CMC Review**

**1. Manufacturing process related to viral clearance:**

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The risk of contamination of Anascorp<sup>®</sup> by viruses of equine origin is of concern. The sponsor implemented three manufacturing to reduce the risk:

- 1) Enzymatic Digestion with Pepsin
- 2) Precipitation with Ammonium Sulfate Combined with Heat Treatment
- 3) Nanofiltration with -----(b)(4)-----

These procedures utilize different mechanisms to remove/inactivate viruses. Through small-scale studies on a range of model viruses that mimic the production process, the sponsor provides viral validation data to support the approval of this BLA.

**2.2. Selected viruses for viral validation**

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