



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

To: STN: 125335.0

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Applicant: Rare Disease Therapeutics. Inc.

Product: Centruroides (Scorpion) Immune F(ab)₂ Intravenous (Equine)
Trade name: Anascorp[®]

Subject: Final Review

Recommendation

Approval

CMC Review

1. Manufacturing process related to viral clearance:

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2. Viral Validation

2.1. Virus clearance by manufacturing steps

The risk of contamination of Anascorp® 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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