

**NDA 22-349**  
**AI-700 - Injectable Suspension**  
**[Perflubutane Polymer Microspheres]**

**FDA Questions**  
**Cardio-Renal Drug Advisory**  
**Committee**

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# Questions

**Please advise and comment on the:**

- **Efficacy data**
- **Safety data**
- **Benefit and risk assessment**

# Question # 1

**Please discuss the extent to which the phase 3 data provide persuasive evidence of diagnostic efficacy:**

- **Consistency between the studies**
- **Comparator (SPECT) performance**
- **Added value to non-contrast ECHO**

## Question # 2

**Please discuss the extent to which the phase 3 data provide persuasive evidence of safety:**

- Rate and nature of acute reactions necessitating AI-700 discontinuation
- Safety database size/single arm study design/stress as confounder
- Exploratory biomarkers of inflammation

## Question # 3 (Vote)

**Does contrast enhancement of rest/stress echocardiography with AI-700 provide sufficient diagnostic benefit to justify the risks associated with the product?**

# Question # 4

Please discuss the need, if any, for additional studies:

- **pre-marketing**
- **post-marketing**
- **nature of studies:**
  - **efficacy**
  - **safety**
  - **controls**

**THANK YOU**