Cardiovascular and Renal Drugs Advisory Committee Meeting

New Drug Application 22-349
AI-700 - Injectable Suspension
[perflubutane polymer microspheres]

December 10, 2008
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Echocardiography contrast agents

- ~ 7 micron bubble/porous sphere
- gas + molecular shell or matrix
- contrast-enhancing acoustics

AI-700 Echocardiography:

- imaging tool to assist in CAD detection
- rest/stress technique
2007/2008 Labeling Changes for Approved Agents

• Assess for contraindications
• Monitor closely patients with pulmonary hypertension or unstable cardiopulmonary conditions
• Resuscitation equipment/personnel available

WARNING: Serious Cardiopulmonary Reactions

Serious cardiopulmonary reactions, including fatalities, have occurred during or following perfluorcarbon-containing microsphere administration.
June 24, 2008 Advisory Committee
Safety of Ultrasound Contrast Agents

- Safety may require R, C studies
- Premarket patients representative of post-market patients
- Post-marketing studies to characterize important but uncommon reactions
- Animal studies may provide cardiovascular safety signals
Diagnostic Effectiveness:

- **Efficacy** may be based upon performance characteristics: sensitivity, specificity

- “Benefit” may be self-evident and not need to be established in studies

- “Benefit” must be:
  - self-evident or
  - established in clinical studies

- **AI-700**: performance characteristics
Risk and Benefit Assessment

- Understanding of:
  - diagnostic information importance
  - risks, including misdiagnosis

- Ultimate risk : benefit assessment:
  - similar to other drugs
Agenda

- Acusphere Summary
- Break
- FDA Summary and Introduction to Questions
- Lunch
- Open Public Hearing
- Afternoon Discussions