

Cardiovascular and Renal Drugs Advisory Committee Meeting

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

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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

WARNING: Serious Cardiopulmonary Reactions

Serious cardiopulmonary reactions, including fatalities, have occurred during or following perflutren-containing microsphere administration.

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

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**

Guidance for Industry

**Developing Medical Imaging Drug and
Biological Products**

Part 1: Conducting Safety Assessments

Guidance for Industry

**Developing Medical Imaging Drug and
Biological Products**

Part 2: Clinical Indications

Guidance for Industry

**Developing Medical Imaging Drug and
Biological Products**

**Part 3: Design, Analysis, and
Interpretation of Clinical Studies**

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**