

# Teleconference Minutes

**Date:** November 5, 1998      **Time:** 3:30 p.m. EST

**Sponsor:** Institute for Clinical PET (ICP)

**Type of Meeting:** Information

**FDA Attendees:**

Jane Axelrad, Associate Director of Policy, Center for Drug Evaluation and Research  
Kim Colangelo, Executive Secretary, PET Steering Committee

**External Attendees:**

Jennifer Keppler, Executive Director, ICP

**Meeting Objective:** to convey information about upcoming public meeting

**Discussion:**

- the meeting will begin with an overview of work done
- preliminary results from the ammonia review will be given, including how the review was approached
- the FDG review is not yet complete; cardiac indications will be discussed
- if the literature is inadequate to support an indication, then discussion will include how to provide the support for the indication
- additional meetings will be scheduled in January and March for further discussion of clinical issues, and other topics (e.g., GMP regulations)
- tentatively, table participants representing ICP include Jorge Barrio, Peter Conti, Jennifer Keppler, Ed Coleman, Peter Valk, and Ruth Tesar; FDA representatives include Jane Axelrad, Florence Houn, Patricia Love, and Victor Raczowski
- ICP will also make opening statements

**Action Items:**

- An agenda and a list of issues for discussion will be provided to ICP prior to the meeting.
- Ms. Keppler will provide a copy of her notes from the August 27, 1998, public meeting to Ms. Axelrad.

98D-0266

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