



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Date: July 12, 2001  
From: Hany Demian, M.S.  
Executive Secretary, Orthopaedic and Rehabilitation Devices Advisory Committee  
Acting Branch Chief of the Orthopaedics Devices Branch  
To: Panel Members  
Subject: Contents of This Mailing

Panel Members:

This memo is intended to describe the contents of this mailing. This shipment includes:

- FDA Panel Pack
  - Tab 1: Panel Questions: Panel members should be able to address each panel question at the meeting.
  - Tab 2: Review Memo from Lead Reviewer dated July 10, 2001.
  - Tab 3: Review Memo from Clinical Reviewer dated July 11, 2001.
  - Tab 4: Review Memo from Statistical Reviewer dated July 12, 2001.
  - Tab 5: Amendment 3 Additional Information dated July 10, 2001\*
- Petition for Reclassification of Metal on Metal Semi-Constrained Hip Joint Prosthesis: 4 Volumes

\* Note: This amendment has not yet been reviewed by FDA. We will comment on this amendment before the panel meeting.

This information is intended to provide you with sufficient details to allow for an objective and focused review of the petition.

If you have any questions regarding the content of this package or your responsibilities during the panel meeting, please feel free to contact me via either e-mail ([hwd@cdrh.fda.gov](mailto:hwd@cdrh.fda.gov)) or by phone (301-594-2036 extension 184).

Sincerely,

Hany Demian, M.S.  
Executive Secretary, Orthopaedics and Rehabilitation Devices Advisory Committee  
Acting Branch Chief of the Orthopaedics Devices Branch