



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

May 11, 2011

OARSI FDA Initiative Executive Committee
15000 Commerce Parkway
Suite C
Mt. Laurel, NJ 08054

RE: OARSI Report for [Docket No. 1998D-0077 (formerly 98D-0077)]
Clinical Development Programs for Human Drugs, Biological Products, and
Medical Devices for the Treatment and Prevention of Osteoarthritis

Dear Members of the Committee,

I would like to thank you for your report based on your critical appraisal of the science related to the design of clinical development programs for human drugs, biological products, and medical devices for the treatment and prevention of osteoarthritis. It is apparent that tremendous effort was involved in compiling this report and we appreciate the time required to gather and convey your recommendations to us.

We have reviewed your report and we agree that your comments have addressed certain points to consider for revising the current osteoarthritis guidance. Your findings also highlighted vital issues that could benefit from further research such as approaches for clinical trial design and analysis, endpoints and progression of disease.

We plan to proceed with efforts to address specific issues discussed in your report and look forward to future opportunities for engagement. Your efforts are much appreciated and I look forward to interacting with OARSI.

Sincerely,

A handwritten signature in black ink, appearing to read "Janet Woodcock".

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research