APPENDIX A:

Sample Schedule of
Study Visits and Evaluation

SAMPLE SCHEDULE OF STUDY VISITS AND EVALUATION

Visit Description	Screening	Treatment and Follow-up						
Study Visits/ Study days (or weeks)	Visit -1 Day -14 to Day -1	Visit 1 Day 0 Randomization	Visit 2 Week 2	Visit 3 Week 4	Visit 4 Crossover Week 8	Visit 5 Week 10	Visit 6 Week 12	Visit 7 Week 16 End of Study
Informed Consent	X							
Demographics								
Joint Exam		X			X			X
Medical History	X	X	X	X	X	X	X	X
Prior Medications	X							
Physical Exam	X							X
Blood Pressure	X	X	X	X	X	X	X	X
Height	X	X	X	X	X	X	X	X
Weight	X	X	X	X	X	X	X	X
Muscle Strength Test	X	X	X	X	X	X	X	X
Chemistries	X	X		X	X	X	X	X
Liver and Kidney Function Tests	X	X	X	X	X	X	X	X
Hematology	X	X	X	X	X	X	X	X
Pregnancy Test	X	X			X	X	X	X
Randomization		X						
Intervention Administration		X	X	X	X	X	X	
Concomitant Medications	X	X	X	X	X	X	X	X
Adverse Events		X	X	X	X	X	X	X
Study Completion								X