U.S. Food and Drug Administration

Department of Health and Human Services

CDER PUBLIC MEEETING

SUPPLEMENTS AND OTHER CHANGES TO AN APPROVED APPLICATION

Wednesday, February 7, 2007

8:30 AM – 3:30 PM

Food and Drug Administration
7519 Standish Place, 3rd Floor, Room A
Rockville, MD 20855

8:30 Opening Remarks
Helen Winkle
Director, Office of Pharmaceutical Science (OPS)

8:35 Center for Drug Evaluation and Research (CDER) Perspective
Douglas Throckmorton
Deputy Director, CDER

8:45 OPS Perspective
Jon E. Clark
Associate Director, Immediate Office, OPS

9:05 OPS Review Staff Perspective
Vilayat Sayeed
Division Director, Office of Generic Drugs, OPS

9:25 OPS Review Staff Perspective
Eric Duffy
Division Director, Office of New Drug Quality Assessment, OPS

9:45 Office of Compliance Perspective
Rick Friedman
Division Director, Office of Compliance

10:05 *Break*

10:25 Consumer
Janet Ritter

10:45 Generics Pharmaceutical Association (GPhA) Perspective
Rich Stec
Hospira, Inc.,
Vice-president, Regulatory Affairs

11:05 Pharmaceutical Research and Manufacturers of America (PhRMA) Perspective
Leo Lucisano
GlaxoSmithKline, Regional Director, CMC Regulatory Affairs – Post-Approval

11:35 Consumer Healthcare Products Association (CHPA) Perspective
Fred Razzaghi
Director, Technical Affairs

12:05 *Break*

12:25 SST Corporation
Arthur Fabian
Executive Director, Technical Affairs

12:55 I. Q. Auditing
Calvin Koerner
Consultant

1:25 Genentech Inc.
Earl S. Dye
Director, Regulatory Policy and Liaison

1:35 Closing Remarks
Helen Winkle

1:40 Adjourn