

International Generic Pharmaceutical Association (IGPA)
Conference Workshop – Subsequent Entry Biologics in Canada

September 30, 2009

St Antoine, 9th floor, Le Westin Montreal, Canada

Workshop Directors: Bruce Clark, Apotex Inc.

Kwasi Nyarko, Biologics and Genetic Therapies Directorate, Health Canada

Program

8:30 - 9:00 Registration

9:00 – 9:10 Opening Remarks from Workshop Co-Chairs

9:10 – 9:40 Alan Sheppard, IMS Health

Current Trends within the Global Biotech sector and Impact of Biosimilars

9:40 – 10:10 Kwasi Nyarko, Biologics and Genetic Therapies Directorate, Health Canada

Regulatory Considerations for SEBs in Canada

10:10 – 10:40 Anne Bowes, Office Of Patented Medicines and Liaisons, Health Canada

Second Entry Biologics - Patented Medicines (NOC) Regulations and Data Protection

10:40 – 11:00 Networking Break

11:00 – 11:15 Anthony Ridgway, BGTD, Health Canada

Health Canada Perspective on SEBs: Demonstrating Comparability and other Quality Related Issues

11:15 – 12:00 Question and Answers

12:00 – 1:00 Lunch

1:00 – 2:00 Agnes Klein, BGTD, Health Canada

Subsequent Entry Biologics in Canada: Regulatory Considerations: Clinical Aspects

2:00 – 2:20 Questions and Answers

2:20 – 2:50 Bruce Clark, Apotex Inc.

SEBs in Canada: Generic Industry Perspective

2:50 – 3:20 Bob Nakagawa, Ministry of Health Services, British Columbia

SEBs in the Canadian marketplace

3:20 – 4:00 **Panel Discussion** - One minute recaps from speakers from day.