

US FDA Inspection History

- **1994 – Edison Drive Facility**
GMP Facility Inspection
January 28 & 31, February 04 & 07
- **1996 – Edison Drive Facility**
Pre-Approval Inspection (PAI): 1 drug substance
May 26, 27, & 28
- **1998 – Edison Drive Facility**
GMP Facility Inspection
May 7, & 8
- **2001 – Edison Drive Facility**
GMP Facility Inspection
September 19 & 20
- **2003 – Edison Drive Facility**
Pre-Approval Inspection (PAI): 2 drug substances
July 18, 21, 22 & 24
- **2004 – Edison Drive Facility**
Pre-Approval Inspection (PAI): 1 drug substance
April 21, 22, 23, 26, & 27
No Form 483 Issued
- **2005 – Washington Drive and Edison Drive Facilities – kilo laboratories only**
Pre-Approval Inspection (PAI): 1 drug substance
GMP Facility Inspection
November 2, 3, 4, 7, & 9
- **2007 – Washington Drive and Edison Drive Facilities**
Pre-Approval Inspection (PAI): 3 drug substances
GMP Facility Inspection
April 27 & 30 May 1, 2, 3, & 4
No Form 483 Issued
- **2009 – Washington Drive and Edison Drive Facilities**
Pre-Approval Inspection (PAI): 1 drug substance
GMP Facility Inspection
July 27, 29, 30, 31 & August 4

Korean FDA Inspection History – Edison Drive Facility

- 2004 – Pre-Approval Inspection (PAI): 1 drug substance
April 21, 22, & 23
No Observations Issued