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CONFIDENTIAL

CGIRB Part 11 Compliance Statement

The US Food and Drug Administration (FDA) (the “Agency”) published regulations governing electronic records and electronic signatures, 21 CFR Part 11 (hereinafter referred to as “Part 11”), on 20 March 1997 (62 Federal Register 13430). Part 11 became effective on 20 August 1997. As required by Part 11, CGIRB sent a letter to the FDA on 23 January 2009 certifying that CGIRB recognizes that electronic signatures are the legally binding equivalent of traditional handwritten signatures.

CGIRB utilizes electronic records and electronic signatures for regulated activities. Electronic records are created, modified, maintained, archived, retrieved, or transmitted in support of regulated activities. All business critical electronic systems are validated in a manner compliant with applicable regulatory requirements, including 21CFR Part 11 regulations.