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Appendices are on the CD (located in the back of this report)

Appendix A — Guidance for Industry — E6 Good Clinical Practice Guidance: Consolidated Guidance

Appendix B — Guidance for Industry — Computerized Systems Used in Clinical Investigations

Appendix C — CDRH Warning Letter to Robert Bishop, President of Silimed, Inc.

Appendix D — Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Frequently Asked Questions About Device Trials