

E) ATTACHMENTS

Copies of the literature searches and bibliography of scientific articles are located in Section L of this binder. Each referenced publication, as well as any other materials referenced to herein or that are part of the basis for this petition can be found in the accompanying binders labeled Attachment E (Part 1 and Part 2) respectively. To the best of Petitioner's knowledge, all non-clinical studies were conducted in compliance with good laboratory practice regulations set forth in 21 CFR Part 58 or were exempt from such regulations at the time of conduct or were conducted for experimental research purposes only in academic facilities not expressly intended for formal FDA submission. To the best of Petitioner's knowledge, all clinical studies were conducted in compliance with the requirements for institutional review set forth in 21 CFR Part 56 or were not subject to such requirements in accordance with 21 §CFR 56.104 or 56.105 and were conducted in conformance with the requirements for informed consent set forth in 21 CFR §50.