

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: James Urbanic, M.D.
Radiation Oncology

From: Chair, Institutional Review Board

Date: 11/27/2013

Subject: Human Protocol: IRB00012793
A Randomized Phase II Dose Finding Study of ArginMax for its Effect on Erectile
Function and Quality of Life in Survivors of Prostate Cancer Previously Treated with
Radiotherapy
Sponsor Title: Amendment 5 closure

Study Documents:

Protocol Version: 98110 Am 3 Protocol wo tracking; Informed Consent Version: 98110 Am 3 consent wo tracking (approved); Investigator's Brochure: Male ArginMax Ingredients List ; Advertisements: Patient Flyer, Recruitment Letter; Other Documents: Appendix 1, Appendix 10, Appendix 11, Appendix 12, Appendix 13, Appendix 14, Appendix 15, Appendix 16, Appendix 2, Appendix 3, Appendix 4, Appendix 5, Appendix 6, Appendix 7, Appendix 8, Appendix 9

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

The accrual goal has been reached. The study is closed to accrual.

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.



Richard Weinberg, M.D.