Date: \_\_\_\_\_\_\_\_\_

Eugene Rosenthal, PhD

Office of Biotechnology Activities

National Institutes of Health

6705 Rockledge Drive, Suite 750

Bethesda, MD 20817

Subject: Delegation of Reporting Requirements for drug product

Title: title

NIH Protocol:# ­­­­­­­­­­­ ????

Dear Dr. Rosenthal,

The purpose of this letter is to inform you that on my behalf Sponsor will submit the documents for the above referenced protocol in compliance with the requirements set forth in Appendix M-1-A, Requirements for Protocol Submission of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. Please note that we delegate to the Sponsor the reporting to NIH OBA, of the following documents:

1. Reports as described in M‐1‐B‐1 “Initial RAC Review” (and M‐1‐C-2 “Additional Clinical Trial Sites”) are delegated to Sponsor .
2. Annual reports as described in M‐1‐C‐3 “Annual Reports” are delegated to Sponsor .
3. Safety reports as described in M‐1‐C‐4 “Safety Reporting” will be submitted to our local IBC and Sponsor. Sponsor will send Safety Reports to NIH OBA.

The Sponsor’s contact person is:

Name(s),

address,

telephone

fax numbers

email

Please contact Sponsor contact name with any questions.

Sincerely,

Name PI

Title