Office of Orphan Products Development
Food and Drug Administration
WO32- 5295
10903 New Hampshire Avenue
Silver Spring, MD 20993

DEC 17 2018

Cancer Research and Life Foundation
2015 Placentia Avenue
Costa Mesa, CA 92627

Attention: Ken Rose
Authorized Representative
krose@cssilifesciences.com

Re: Designation request # DRU-2018-6640
Dated: October 3, 2018
Received: October 9, 2018

Dear Mr. Rose:

This letter responds to your request for orphan-drug designation of poly (lactide-co-glycolide)-polyethylene glycol nanoparticles encapsulating quercetin for "treatment of tumor progression in patients with glioblastoma."

Pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), your orphan-drug designation request of poly (lactide-co-glycolide)-polyethylene glycol nanoparticles encapsulating is granted for *treatment of glioblastoma*. Please be advised that it is the active moiety or principal molecular structural features of the drug[1] and not the formulation of the drug that is designated.

If your drug receives marketing approval for an indication broader than what is designated, it may not be entitled to exclusive marketing rights under section 527 (21 U.S.C. 360cc). Therefore, prior to submission of your marketing application, we request that you compare the drug's orphan designation with the proposed marketing indication and submit additional information to amend the orphan-drug designation if warranted. 21 CFR 316.26.

If the same drug is approved for the same indication before you obtain marketing approval of your drug, you will have to demonstrate that your drug is clinically superior to the

[1] The term "drug" in this letter includes drug and biological products.

Cancer Research and Life Foundation

cc:

OOPD/File # DRU-2018-6640

History:
J. Fritsch 12/10/18

DESIGNATION GRANTED