U.S. FOOD & DRUG ADMINISTRATION

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

DEC 19 2017

Coté Orphan, a QuintilesIMS Company
8630 Fenton Street, Suite 724
Silver Spring, MD 20910

Attention: Malia Segar, MS
Associate Director of Regulatory Affairs
malia.segar@quintiles.com

Re: Designation request # DRU-2017-6165
Dated: October 31, 2017
Received: November 1, 2017

Dear Ms. Segar:

This letter responds to your request submitted on behalf of Enzychem Lifesciences Corporation for orphan-drug designation of 1-palmitoyl-2-linoleoyl-3-acetyl-rac-glycerol for "treatment of acute radiation syndrome."

Pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), your orphan-drug designation request of mosedipimod is granted for *treatment of acute radiation syndrome*. 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.

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

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 already approved same drug in order to obtain orphan-drug exclusivity. Failure to demonstrate clinical superiority over the already approved same drug will result in your drug not receiving orphan-drug exclusivity. 21 CFR 316.34(c).

You must submit to the Office of Orphan Products Development a brief progress report of drug development within 14 months after this date and annually thereafter until marketing approval. 21 CFR 316.30.

Please notify this Office within 30 days of submitting a marketing application for the drug's designated use. Once your marketing application is approved, please contact Jeffrey Fritsch, RPh at 301-796-8682 or alternatively at 301-796-8660 to assess eligibility for orphan-drug exclusivity.

If you have questions regarding the development of your designated product, please feel free to contact Erica K. McNeilly, RPh, at 301-796-8679 or alternatively at 301-796-8660. Congratulations on obtaining your orphan-drug designation.

Sincerely,

for Debra Y. Lewis, OD, MBA
Acting Director
Office of Orphan Products Development