



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of Orphan Products Development
Food and Drug Administration
Building 32, Room 5271
10903 New Hampshire Avenue
Silver Spring, MD 20993

JAN 12 2011

Epitopoietic Research Corporation (ERC)
1055 E. Colorado Blvd.
Suite 5 Floor 5
Pasadena, California 91106

Attention:

Re: Designation request # 10-3292

Dear

Reference is made to your request for orphan-drug designation submitted October 28, 2010, of glioma derived cell lysates and irradiated cells for "treatment of glioma." Please also refer to our letter dated December 1, 2010.

Pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), your request for orphan-drug designation of glioma derived cell lysates and irradiated cells is granted for *treatment of glioma*. Please be advised that it is the active moiety of the drug and not the formulation of the drug that is designated.

Please note that if the above 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 final marketing approval, we request that you compare the drug's designated orphan indication with the proposed marketing indication, and submit additional information to amend the orphan-drug designation if warranted.

Epitopoietic Research Corporation (ERC)

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Please 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 (*see* 21 C.F.R. 316.30). Finally, please notify this Office within 30 days of a marketing application submission for the drug's designated use.

If you have questions regarding the development of your designated product, please feel free to contact Soumya Patel, Pharm.D., Please refer to this letter as
official notification. Congratulations on obtaining your orphan-drug designation.

Sincerely yours,



Timothy R. Cote, M.D., M.P.H.
Director, Office of Orphan Products Development