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

MAY 14 2012

Unicorn Pacific Corporation
P.O. Box 750145
Forest Hills, New York 11375

Attention: Marlena Shell
Vice President of U.S. Operations

Re: Designation request # 12-3686

Dear Ms. Shell:

Reference is made to your request for orphan-drug designation submitted on March 12, 2012, of extract of sea cucumber, sea sponge, shark fin, sea urchin, and sargassum marine grass (company name: TBL-12) for "treatment of multiple myeloma (MM)." Please also refer to our letter dated March 26, 2012.

Pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), your orphan-drug designation request of extract of sea cucumber, sea sponge, shark fin, sea urchin, and sargassum marine grass (company name: TBL-12) is granted for *treatment of multiple myeloma.* 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.

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 James D. Bona, R.Ph., M.P.H., at (301) 796-8660. Please refer to this letter as official notification. Congratulations on obtaining your orphan-drug designation.

Sincerely yours,

Gayatri Rao

Gayatri R. Rao, M.D., J.D.
Acting Director
Office of Orphan Products Development