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

Date

Name and Address of Sponsor

Re: Designation request #

Dear Sponsor:

This letter is to update you about your orphan drug designation by informing you how your designation is listed on our website at www.fda.gov/orphan. The Food and Drug Administration (FDA) publishes the "generic name and/or trade name" of a drug after it designates that drug as an orphan drug. It has come to our attention that your product that received orphan drug designation is published on our public database using a non-informative identifier. After careful consideration of this matter, we have concluded that the Orphan Drug Act mandates that the FDA identify to the public products that have received orphan drug designation. Typically, we provide this required public notice of an orphan drug by publishing its established or trade name. If, as is the case here, a drug has no established or trade name, publishing a non-informative identifier does not meet the statutory disclosure requirement because the public would not be able to clearly identify the drug that has been designated as an orphan drug.

The Orphan Drug Act aims to promote information about an orphan drug's potential for exclusivity in order to properly incentivize sponsors of such drugs. Allowing sponsors to obscure the identity of their orphan drug candidates would create uncertainty with regards to which sponsors may ultimately benefit from orphan drug exclusivity and would thus undermine the incentive structure that Congress has sought to establish.

Therefore, in order to effect public notice of your drug's orphan status as required under the Orphan Drug Act, we have removed the non-informative code for your drug that is currently on our website and replaced it with an informative identifier. This identifier can be located at the website www.fda.gov/orphan under "Resources for You". Click on the "Search for Orphan Drug Designations and Approvals" and enter your product. If you do not believe that the identifier that we have chosen on the website accurately identifies your product, please contact our office within 20 days from the date of this letter.

We appreciate your work on the development of products for rare diseases. If you have any questions concerning this matter, you may contact Jeffrey Fritsch, R.Ph., in this Office at 301-796-8682.

Sincerely yours,

Debra Y. Lewis, O.D., M.B.A.
Acting Director
Office of Orphan Products Development