



Office of Orphan Products Development (HF-35)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

August 9, 2006

Autoimmunity Research Foundation
3423 Hill Canyon Avenue
Thousand Oaks, California 91360

Attention: Trevor G. Marshall, PhD
Director

Re: Designation Request # 05-2134

Dear Dr. Marshall:

Reference is made to your request for orphan-drug designation submitted September 20, 2005, of clindamycin for "treatment of sarcoidosis." We refer also to our letters of September 29 and December 15, 2005, and March 28, 2006, and to your submissions dated January 10, February 13, and May 19, 2006.

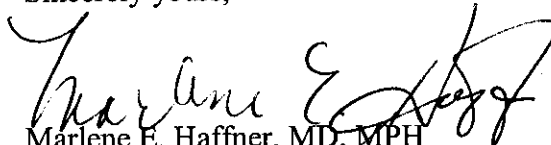
Pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), your request for orphan-drug designation of clindamycin is granted for *treatment of sarcoidosis*. Please be advised that it is clindamycin and not the formulation of the drug that is designated.

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 need further assistance in the clinical development of your drug, please feel free to contact Peter L. Vaccari, R.Ph., RAC, at (301) 827-3666. Please refer to this letter as official notification. Congratulations on obtaining your orphan-drug designation.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Marlene E. Haffner". The signature is fluid and cursive, with a large initial "M" and "H".

Marlene E. Haffner, MD, MPH
Rear Admiral, United States Public Health Service
Director, Office of Orphan Products Development