

Food and Drug Administration  
Rockville MD 20857

6641 '04 MAR -1 09:38

Re: Iprivask  
Docket No.: 03E-0419**FEB 25 2004**

The Honorable James E. Rogan  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Pat. Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 4,745,177, filed by Novartis Corporation and UCP Gen-Pharma AG, under 35 U.S.C. section 156 *et seq.* We have reviewed the dates contained in the application and have determined the regulatory review period for Iprivask, the human drug product claimed by the patent.

The total length of the regulatory review period for Iprivask is 4,707 days. Of this time, 3,696 days occurred during the testing phase and 1,011 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 17, 1990.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 17, 1990.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: June 28, 2000.

FDA has verified the applicant's claim that the new drug application (NDA) for Iprivask (NDA 21-271) was initially submitted on June 28, 2000.

3. The date the application was approved: April 4, 2003.

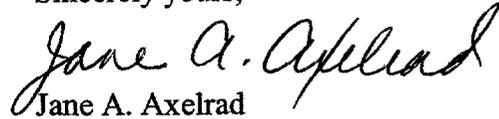
FDA has verified the applicant's claim that NDA 21-271 was approved on April 4, 2003.

**03E-0419****LET 4**

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Thomas Hoxie  
Vice President, Head of Intellectual Property  
Novartis Corporation  
Corporate Intellectual Property  
One Health Plaza  
East Hanover, NJ 07936-1080