

February 2, 2004

Ms. Shalini Jain  
Advisors and Consultants Staff, HFD-21  
OEP/CDER  
Food and Drug Administration  
Room 1093  
5630 Fishers Lane  
Rockville, Maryland 20857

Ladies and Gentlemen:

**Re: Isotretinoin Capsules, USP**  
**Amnesteem, ANDA 75-945 – Mylan/Bertek<sup>1</sup>**  
**Sotret, ANDAs 76-041 and 76-503 – Ranbaxy**  
**Claravis, ANDAs 76-135 and 76-356 – Barr Laboratories**

**General Correspondence: Addendum to the January 25, 2004 Roche Advisory  
Committee Meeting Briefing Document**  
**AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION**

Reference is made to the upcoming advisory meeting of the Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Advisory Committee on February 26 and 27, 2004. This addendum is submitted on behalf of the following generic companies who market or manufacture isotretinoin capsules:

Mylan/ Bertek  
Ranbaxy  
Barr  
Genpharm

All the above Companies have agreed to the content of the addendum. The Companies agree in principle with the Roche proposed risk management program submitted to the Agency on Jan. 25, 2004 with a few exceptions and clarifications. The purpose of this Addendum is to comment on the Roche proposal.

Please find enclosed 60 copies of the Addendum to the January 25, 2004 Roche Advisory Committee Briefing Package to support this meeting.

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<sup>1</sup> Genpharm is the manufacturer and owner of the ANDA.

This submission also provides 1 diskette containing Microsoft Word files of the documents that are available electronically. Also enclosed is 1 diskette containing Acrobat files (pdf file) of the same documents.

Please do not hesitate to contact me if you have any questions regarding this package.

Sincerely,

Barr Laboratories, Inc.

Christine Mundkur  
Sr. Vice President Quality and Regulatory Counsel  
Telephone: (201) 930-3600  
Fax: (201) 930- 3318

Enclosures

cc: Dr. Steven Galson, (1 desk copy)  
Dr. Jonca Bull (1 desk copy)  
Gary Buehler (1 desk copy)  
Dr. Paul Selligman (1 desk copy)  
Dr. Jonathon Wilkin (1 desk copy)  
Dr. Ann Trontell (1 desk copy)  
Ms. Mary Jean Kozma-Fornaro (5 desk copies)  
Mr. Patrick Guinn (5 desk copies)