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VIA ELECTRONIC SUBMISSION

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**Re: Request For Extension Of Comment Period: Docket No. 2004N-0355,
Scientific Considerations Related To Developing Follow-On Protein
Products**

Dear Sir or Madam:

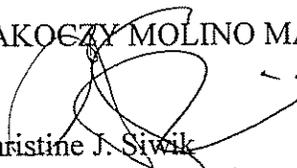
Barr Laboratories, Inc. (Barr) hereby requests an extension of the comment period for the above referenced Docket. Barr is in the process of investigating and analyzing various issues involved in creating a pathway for an abbreviated approval process for generic biopharmaceuticals and the specific questions raised by the Agency in its Federal Register Notice, 69 Fed. Reg. 50386 (Aug. 16, 2004). Barr also was a presenter at the September 14-15, 2004 public workshop on scientific and technical considerations related to the development of follow-on protein pharmaceutical products, and would like to address some of the positions and questions raised at the workshop in its comments.

Due to the complex nature of these issues and their significance to the biopharmaceutical industry, Barr requests a 30-day extension of the comment period to provide FDA with an analysis that addresses the technological and safety issues of primary concern to the Agency.

Thank you for your consideration.

Very truly yours,

RAKOCZY MOLINO MAZZOCHI SIWIK LLP


Christine J. Siwik
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