

## ADMINISTRATIVE HISTORY

### CBER Review Committee

Product/Committee Chair:	Terrye Zaremba, Ph.D.
Product Review Staff	Terrye Zaremba, Ph.D., Product Reviewer Leon Epps, Ph.D., Radiation Chemistry Reviewer Keith Webber, Ph.D. Dep. Div. Director
Clinical Review Staff:	Kathryn Stein, Ph.D., Director, DMA Steven Litwin, M.D., Medical Reviewer George Mills, MD, Medical Reviewer, Branch Chief Harvey Luksenburg, M.D., Medical Reviewer Kaushik Shastri, M.D., Medical Reviewer Susan Jerian, M.D., Team Leader Patricia Keegan, M.D., Dep. Div. Director DCTDA
Biostatistical Review Staff:	Satish C. Misra, Ph.D. Ghanshyam Gupta, Ph.D., Branch Chief Peter A. Lachenbruch, Ph.D., Div. Director
Clinical Toxicology & Pharmacology: Regulatory Project Manager:	David Green, Ph.D., Branch Chief, Mike Noska Karen Jones
Compliance/BIMO:	Mary Andrich, M.D.

**Sponsor:** Corixa Corporation

**Product:** Bexxar (Proprietary name); Tositumomab (murine monoclonal antibody directed against the CD20 antigen) and Iodine I-131-labeled Tositumomab (USAN names)

### Proposed indication in Original BLA September 14, 2000

“Iodine I 131 tositumomab is indicated for the treatment of patients with relapsed or refractory low-grade or transformed low-grade, CD20-positive, B-cell non-Hodgkin’s lymphoma.”

### Revised indication submitted -----

Corixa submitted a request for standard approval of Bexxar based on demonstration of efficacy in patients with Rituximab refractory follicular non-Hodgkin’s lymphoma. In addition, Corixa requested accelerated approval based on the existence of long-term durable responders (time-to-progression [TTP] of at least one year) in patients with relapsed or refractory, follicular or transformed non-Hodgkin’s lymphoma and who were culled from multiple clinical studies.

The revised proposed indication being sought is  
“BEXXAR® is indicated for the treatment of patients with relapsed or refractory low-grade, follicular or transformed low-grade B-cell non-Hodgkin’s lymphoma (NHL) including patients with Rituximab refractory follicular non-Hodgkin’s lymphoma. Determination of the effectiveness of the BEXXAR therapeutic regimen in relapsed or refractory patient population is based on the existence of long-term durable responders (time-to-progression [TTP] of at least one year) in multiple clinical studies.”

**Regulatory history**

The Investigational New Drug Application (IND) for Bexxar was received on October 13, 1989.

**Milestones prior to submission of BLA**

[

06/29/99      BLA Application (STN 103906/0) Submitted ]  
08/27/99      FDA Refusal-to-file (RTF) Letter Issued

**Milestones for BLA STN 125011/0**

09/14/00      BLA Application (STN 125011/0) Submitted  
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03/16/01      FDA Complete Review (CR) Letter Issued ]  
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03/12/02      FDA Complete Review Letter Issued ]  
[

05/31/02      Request for Dispute Resolution Submitted ]

06/26/02     FDA Other Letter re: Dispute Resolution Issued  
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