



Our STN: BL 103946/5017

DEC 15 2004

Sanofi-Synthelabo, Incorporated
Attention: Mark Gaydos
Director, Promotion, Review and Labeling
U.S. Regulatory Affairs
90 Park Avenue
New York, NY 10016

Dear Mr. Gaydos:

Your request to supplement your biologics license application for Rasburicase to revise the Anaphylaxis subsection of the WARNINGS section of the package insert has been approved.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please refer to <http://www.fda.gov/cder/biologics/default.htm> for important information regarding therapeutic biological products, including the address for submissions. Effective October 4, 2004, the new address for all submissions to this application is:

CDER Therapeutic Biological Products Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
12229 Wilkins Avenue
Rockville, Maryland 20852

This information will be included in your biologics license application file.

Sincerely,

(b)(6)

for Patricia Keegan, M.D.
Director
Division of Therapeutic Biological Oncology Products
Office of Drug Evaluation VI
Center for Drug Evaluation and Research

Enclosure: Revised Labeling

CONCURRENCE PAGE

Letter Type: LETTER: Approval (AP)
Summary Text: Clinical Supplmt. – Labeling Only

SS Data Check:

- Place copy of Approval Ltr. with original signature concurrence page in Archival package behind the “Approval Materials” Tab after LAR (Licensing Action Recommendation).

RIS Data Check:

- Verify short summary – Ltr. & Submission screen should match.
- Perform Review Completion Process
- Milestone: Confirm Approved Status

cc: HFD-107/P. Keegan
HFD-107/R. Justice
HFD-107/J. Gootenberg
HFD-107/P. Dinndorf
HFD-106/K. Weiss
HFD-106/G. Jones
HFD-109/E. Dye
HFD-109/W. Aaronson
HFD-109/K. Jones
HFD-109/J. Condino
HFM-110/RIMS/R. Eastep
HFD-400/ODS M. Dempsey
HFD-430/DDRE J. Chang
HFD-430/DDRE R. Kang
HFD-006/Exec sec P. Guinn
HFD-013/FOI D. Taub
HFD-013/FOI H. Brubaker
HFD-240/OTCOM/ B. Poole
HFD-230/OTCOM/CDER WebMaster
HFD-42/DDMAC/M. Kiester
HFD-410/ODS/DSRCS/ Karen Young
HFD-410/CDER Medwatch Safety Labeling HFD-430/ODS/DDRE (hard copy)
DRMP BLA file (hard copy)

History: J. Condino: 11.23.2004: K. Townsend: 11.23.2004: jc:12.02.04: jc:12.08.04
K. Townsend: 12.2.2004

File Name: (S:\Condino\BLA's\BLA103946\5017LablChg\103946-5017AP

Division	Name/Signature	Date
COEVI / DRMP	(b)(6)	12/08/04, 12/13/04
COEVI / DRMP		12/14/04
DRMP		12-14-04
COEVI / DTBOP		12/15/04
DRMP		12/20/04