DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Office of Orphan Products Development *(HF-35)*
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

November 17, 2004

Torys
237 Park Avenue
New York, New York 10017-2142

Attention: Andrew J. Beck, Esquire
U.S. Contact

Re: Designation request # 04-1925

Dear Mr. Beck:

Reference is made to your request for orphan-drug designation dated July 30, 2004, submitted on behalf of YM Biosciences Inc., of nimotuzumab for the "treatment of glioma." We also refer to our letters of August 3 and September 27, 2004. Please also reference your submission dated October 29, 2004.

Pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), your request for orphan drug designation of nimotuzumab is granted for the *treatment of glioma*. Please be advised that it is nimotuzumab and not the formulation of the drug that is designated.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our Reference: BB-IND 12313

Jean Bello Belasco, M.D.
Clinical Professor of Pediatrics
The Children's Hospital of Philadelphia
Division of Neuro-Oncology
34th Street and Civic Center Boulevard
Philadelphia, PA 19104-4399

Dear Dr. Belasco:

The Center for Drug Evaluation and Research has received your **Investigational New Drug Application (IND)**. The following product name and BB-IND number have been assigned to this application. They serve only to identify it and do not imply that this Center either endorses or does not endorse your application.

BB-IND #: 12313

SPONSOR: Jean Bello Belasco, M.D.

PRODUCT NAME: Nimotuzumab [Humanized Monoclonal Antibody (h-R3, TheraCIM, TheraLoc) (YM Biosciences) to Epidermal Growth Factor Receptor (EGFR)]