



Our STN: BL 125587/0

PROPRIETARY NAME ACCEPTANCE

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
Octapharma USA, Inc.
121 River Street, Suite 1201
Hoboken, NJ 07030

Dear Mr. Ammons:

We have reviewed your submission dated April 15, 2015 to your biologics license application for Immune Globulin Intravenous (Human) 10% requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch, we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, PANZYGA, is acceptable.

If you have any questions, please contact Christopher Hooban, Regulatory Project Manager, at (240) 402-8376 or at christopher.hooban@fda.hhs.gov.

Sincerely yours,

Paul D. Mintz, MD
Director
Division of Hematology Clinical Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research