

Stakeholders Respond to Request for Feedback on Bio-Similars Pathway

Washington, DC – The Committee on Energy and Commerce has released the responses to the questionnaire that was submitted to stakeholders on April 3, 2008, soliciting feedback on how to establish a pathway to allow for the Food and Drug Administration (FDA) to approve bio-similar products.

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Responses Under Review as Pallone, Deal Continue Effort to Develop Balanced Policy

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The
April 3 letter sent from Reps. Frank Pallone, Jr., (D-NJ), Chairman of the Subcommittee on Health, and Nathan Deal (R-GA), ranking Republican of the Subcommittee on Health, can be viewed by clicking [here](#).

“We
hope that these responses will better inform our efforts to craft legislation that can achieve consensus among the Members,” Pallone and Deal said. “We are fully committed to ensuring that FDA has the authority to approve safe, affordable bio-similar products in an appropriate and timely fashion.”

Responses to April 3, 2008 letter to 35 groups in regard to generic versions of biologic products

May 2, 2008
AARP

May 2, 2008
AFL-CIO

May 2, 2008
American Society of Clinical Oncology

May 2, 2008
Amgen

May 2, 2008
Association of American Universities

May 2, 2008
Barr Pharmaceuticals, Inc.

May 2, 2008
Biogen

May 2, 2008
Biotechnology Industry Organization

May 2, 2008
California Healthcare Institute

April 21, 2008
Cell Therapeutics, Inc.

May 2, 2008
Coalition for a Competitive Pharmaceutical Market

May 2, 2008
Consumers Union

May 2, 2008
Federal Trade Commission

September 18, 2008
Food and Drug Administration

April 30, 2008
General Motors

Genetech

May 6, 2008
GlycoMimetics, Inc.

GPHA

April 29, 2008
Insmed Incorporated

Johnson & Johnson

May 2, 2008
Millennium Pharmaceuticals, Inc.

May 2, 2008
Mylan Labs

National Governors Association

National MS Society

May 2, 2008
National Organization of Rare Disorders

May 2, 2008
National Venture Capital Association

May 1, 2008
Novartis Corporation

May 2, 2008
PhRMA

Teva Pharmaceuticals

May 2, 2008
Vertex Pharmaceuticals Incorporated

Prepared by the Committee on Energy and Commerce

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