

June 4, 2012

Commissioner Margaret A. Hamburg
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

Since the draft guidances released by the FDA on February 9, 2012 (“Guidances”) were directed to the process of biosimilar product development and were silent on the issue of biosimilar naming, most of the undersigned groups did not file formal comments to the Guidances. However, biosimilar naming is an important issue for consumers, and each of the undersigned organizations wishes to use this opportunity to articulate our concerns on the matter.

All of the undersigned groups share the FDA’s deep commitment to patient safety. Based on all of the information at our disposal, we believe that biologics and biosimilars should be required to have the same International Nonproprietary Name (INN). Requiring different INNs for biologics and biosimilars could lead to patient and prescriber confusion, increasing the possibility of medication errors, and would also effectively separate the biosimilar from existing safety information about the underlying molecule. In addition, since adverse events and product recalls for small-molecule and biologic drugs are already successfully identified using the national drug code and lot number, there is no compelling evidence that biosimilars should be handled differently.

Further, there is already a precedent for shared names (e.g., erythropoietins, somatropin, interferon), which has not resulted in any known issues. Shared INNs are also safely and effectively utilized in EU, Canada, Australia, and Japan.

We also know from our members that cost is often a barrier to patient compliance with their drug regimens. We are hopeful that the biosimilar approval pathway included in the Patient Protection and Affordable Care Act will lead to less expensive but equally effective alternatives to biologic drugs. However, requiring different INNs would create an unnecessary barrier to the benefits of FDA-determined interchangeability. Patients, prescribers and dispensers of these drugs need to be able to easily identify which drugs bear a relation to one another in order to maximize the potential savings from the biosimilar approval pathway.

Thank you for your careful consideration of this important matter. We welcome the opportunity to work with you to ensure that the new biosimilar market in the United States gives patients access to safe, effective and more affordable alternatives to brand-name biologics.

Yours truly,

AARP

Alliance for Retired Americans

AFL-CIO

American Federation of Federal, State, County and Municipal Employees (AFSCME)

American Federation of Teachers (AFT)

American Medical Students Association

Blue Cross Blue Shield Association

California Public Employees Retirement System

Community Catalyst

Consumer Federation of America (CFA)

Health Care for America Now

International Brotherhood of Teamsters (IBT)

National Association of Chain Drug Stores

National Coalition on Health Care

National Committee to Preserve Social Security and Medicare

Older Women's League

Service Employees International Union (SEIU)

United Automobile, Aerospace and Agricultural Implement Workers of America (UAW)

UAW Retiree Medical Benefits Trust

United Steelworkers (USW)

US Action

US PIRG

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