

American
Autoimmune Related
Diseases Association
(AARDA)

Arthritis Foundation
(AF)

Committee of Ten
Thousand (COTT)

Crohn's and Colitis
Foundation of
America (CCFA)

Dystonia Medical
Research Foundation
(DMRF)

GDS/CIDP Foundation
International

Hemophilia
Federation of America
(HFA)

Hepatitis Foundation
International (HFI)

Immune Deficiency
Foundation (IDF)

International
Foundation for
Autoimmune Arthritis

Jeffrey Modell
Foundation

Lupus and Allied
Diseases Association
(LADA)

Lupus Foundation of
America

National Alliance on
Mental Illness (NAMI)

National Organization
for Rare Disorders
(NORD)

National Psoriasis
Foundation (NPF)

Platelet Disorder
Support Association
(PDSA)

Pulmonary
Hypertension
Association (PHA)

RetireSafe

Scleroderma
Foundation

Spondylitis
Association of
America

United Spinal
Association

US Hereditary
Angioedema
Association (US
HAEA)

US Pain



Robert Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Docket No. FDA-2016-D-0643 Comments Submitted on “Labeling for Biosimilar Products; Draft Guidance for Industry”

Submitted electronically via www.regulations.gov

May 31, 2016

Dear Commissioner Califf:

Patients for Biologics Safety and Access (PBSA) commends the FDA for publishing draft guidance on labeling of biosimilars which is a positive step forward, especially when combined with the FDA's draft guidance calling for biosimilars to have distinct non-proprietary names. We are pleased that the guidance requires products to be clearly labeled as biosimilars and contain standard information about immunogenicity concerns. We believe the final guidance must take additional important steps, including a requirement that biosimilar labels specify which indications were approved based on extrapolation of data rather than clinical testing. Furthermore, we believe that final labeling guidance should require the inclusion of pertinent clinical data and adverse events specific to the biosimilar, as well as a statement declaring whether or not the product has been approved as interchangeable. This information will help patients and prescribers have the necessary facts to make a fully informed choice whether to use the original biologic medicine or biosimilar.

We urge the FDA to incorporate the recommendations included in PBSA's policy position on biosimilar labeling in its final guidance:

Biosimilar Labeling to Promote Transparency and Patient Safety

PBSA believes that patients and prescribers should have all pertinent information to make a knowledgeable decision whether to use an innovative biologic or biosimilar. In addition, adequate material on biosimilars must be available to patients and prescribers in a format that allows them to make such an informed choice that includes clear and transparent product labeling information as a critical component.

PBSA recommends that FDA require biosimilar labeling to include the following information:

- *Statement that the product is a biosimilar;*
- *Statement about whether or not the product has been approved as*

interchangeable with the reference product and the indications of approved use (including any differences from the reference product);

- *Statement of any indications approved on the basis of indication extrapolation;*
- *Other pertinent data (analytical, animal and clinical) derived from studies of the biosimilar that formed the basis of the FDA approval of the product, and;*
- *Any adverse event information specific to the biosimilar.*

Sincerely,

Lawrence A. LaMotte

On behalf of Patients for Biologics Safety and Access

American Autoimmune Related Diseases
Association
Arthritis Foundation
Committee of Ten Thousand
Crohn's & Colitis Foundation of America
Dystonia Medical Research Foundation
GBS/CIDP Foundation International
Hemophilia Federation of America
Hepatitis Foundation International
Immune Deficiency Foundation
International Foundation for Autoimmune Arthritis
Jeffrey Modell Foundation
Lupus and Allied Diseases Association

Lupus Foundation of America
National Alliance on Mental Illness
National Organization for Rare Disorders
National Psoriasis Foundation
Platelet Disorder Support Association
Pulmonary Hypertension Association
RetireSafe
Scleroderma Foundation
Spondylitis Association of America
United Spinal Association
US Hereditary Angioedema Association
US Pain Foundation