



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

Brussels, June 3, 2016

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

International Generic and Biosimilar Medicines Association (IGBA) commentary on FDA's Draft Guidance on Labeling for Biosimilar Products (Docket No. FDA-2016-D-0643)

Submitted electronically via www.regulations.gov

Dear Commissioner Califf,

IGBA thanks the Agency's for providing an opportunity to comment on the Agency's *Draft Guidance on Labeling for Biosimilar Products (Docket No. FDA-2016-D-0643-0001)*. IGBA's position is aligned with the key comments of the Biosimilar Medicines Group, a sector group of Medicines for Europe, which have been submitted separately.

Please find hereby the highlights of this position:

We welcome and support the proposed "same-label" or "reference label" approach, as successfully practiced in Europe since 10 years. This position is coherent with the scientific concepts and principles underlying the biosimilar medicines development, the corresponding legal basis and regulatory approval process. This approach also supports international convergence of a very important aspect for the stakeholders, namely labeling, which is a core element for communication and for safe and effective use of a medicine. We also welcome the clarification that the purpose of the label is not to provide a full development description or life-cycle information.

At the same time, we support the proposed exceptions to the "same-label" approach to accommodate carved-out indications, where deemed necessary.



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We are however very concerned about the proposed FDA naming policy which will trigger, without doubt, confusion and uncertainties among healthcare providers and other stakeholders. The confusion will be amplified by introducing 3 different types of names (core name, proper name and proprietary names) in some sections of the label. Furthermore this approach has the potential to undermine the totality of evidence as a fundamental pillar for the biosimilar medicine approval.

We therefore reiterate here our support to regulators worldwide for their efforts to converge on regulatory policies on naming and labeling (i.e. “same name, same label”). The upcoming meeting in Lisbon of the Biosimilars Working Group of the International Pharmaceutical Regulators Forum (IPRF) provides an excellent opportunity to discuss convergence of key elements related to biosimilar medicines. In order to increase acceptance of these new therapeutic options, convergence remains a must if we wish to foster greater access to modern therapies for more patients in the USA and around the world.

We trust that you are taking these comments into consideration.

Sincerely,

Suzette Kox, Senior Director International - Biosimilar Medicines Group - Medicines for Europe

Chair of the IGBA Biosimilars Committee

About IGBA

The International Generic and Biosimilar Medicines Association (IGBA) was founded as IGPA (International Generic Pharmaceutical Alliance) in March 1997 to strengthen cooperation between associations representing manufacturers of generic medicines. Its membership includes the EGA (Europe), the CGPA (Canada), the GPhA (USA), the JAPM (Jordan), the NAPM (South Africa), the TGPA (Taiwan) and the JGA (Japan) while the associations from Australia (GBMA), Brazil (ProGenericos), Mexico (AMEGI) and recently Malaysia (MOPI) are Associate Members. The IGBA is at the forefront of stimulating competitiveness and innovation in the pharmaceutical sector by providing high quality pro-competitive medicines to millions of patients around the world. Through its constituent member associations, the IGBA maintains constant dialogue with



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government authorities (including the European Commission for Europe) as well as with international institutions such as WTO, WIPO and WHO. More information: www.igbamedicines.com

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