INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

November 12, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

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

Comments of the International Generic and Biosimilar Medicines Association (IGBA) regarding

- Docket FDA-2013-D-1543: Nonproprietary Naming of Biological Products; Draft Guidance for Industry
- Docket FDA-2015-N-0648: Designation of Official Names and Proper Names for Certain Biological Products; Proposed rule

Submitted electronically via www.regulations.gov

Dear Acting Commissioner Califf,

The International Generic and Biosimilar Medicines Association (IGBA), representing member associations from the U.S. (GPhA), Canada (CGPA), Japan (JGA), Jordan (JAPM), Europe (EGA), South Africa (NAPM), and Taiwan (TGPA), as well as associate member associations from Australia (GBMA), Brazil (ProGenericos) and Mexico (AMEGI), thank for the opportunity to share our

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thoughts on the important topic of non-proprietary naming of biological products, including biosimilar products.

The IGBA Member Companies are 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. We are consequently monitoring very closely worldwide any developments which may hamper competition and impact access for patients, in particular non-proprietary naming policies that have the potential to hamper competition.

We strongly believe that biosimilar medicines should share the same INN or proper name with the reference protein product (RPP). Europe has almost 10 years of safe clinical experience with biosimilar products baring the same INN as their respective RPP. The EU regulatory and scientific thinking is that biosimilars should be closely aligned with their RPPs. Identification by INN together with a qualifier or code for each biosimilar would be contrary to such alignment.

We also believe that consistent non-proprietary naming will ensure robust market formation that ultimately supports patient access and affordability, supports pharmacovigilance systems currently in place, allows for unambiguous prescribing, and builds upon the successful foundation of the
global INN system that has been used successfully for more than six decades for both small molecule brand and generic products and large molecule biological products.

We are consequently very concerned about the FDA proposed naming policies. Indeed, creating a new naming convention with unique, meaningless, non-memorable proper names will instill uncertainty, compromise safety and limit ability to improve patient access to biologics. Different suffixes will convey the message that the drug substance in a biosimilar differs in clinically meaningful ways from that in the reference product and will consequently deter physicians from prescribing biosimilars, thus impeding competition. As you know, clinically significant differences between a biosimilar and its reference are explicitly prohibited by the statute, and we are highly confident that FDA can, and will, withhold licensures from proposed biosimilars when such differences are evident. Furthermore, unique names could disrupt the current naming system, and contribute to the proliferation of unique identifiers for the same product around the globe, weakening thereby considerably the international regulatory convergence efforts regarding biosimilars.

We note that the identification of medicinal products in all ICH regions has been tackled in a coordinated fashion over the last few years under the impulse of ICH. It has led to the development of the internationally agreed ISO IDMP (Identification of Medicinal Products) standard which is tailored and tested by users to meet both objectives of identification and traceability. Significant resources are being invested into this international product identifier which is in the process of being implemented in the EU.

We reiterate our support to regulators worldwide for their efforts in prioritizing the need to avoid proliferation of separate and distinct naming by individual regulatory authorities as key to achieving good biologic drugs identification. We call on the U.S. FDA and all regulators to achieve a consensus solution to this global issue. In the meantime, a moratorium on further policies on biologic drugs naming is required until clarity becomes available, further to international regulators' exchange on this important matter.

Thank you for your kind consideration of our proposals.

Sincerely,

Vivian Frittelli, Chair, International Generic and Biosimilar Medicines Association