Hepatitis Foundation International Comments on
"Guidance for Industry Nonproprietary Naming of Biological Products"
October 26, 2015

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As Chief Executive Officer of the Hepatitis Foundation International (HFI) we are honored to be able to share HFI's comments on biosimilars with the FDA for this Draft Guidance. HFI is a 501(c) 3 non- profit organization established in 1994 to eradicate viral hepatitis for 400 million people globally. HFI is also dedicated to increasing and promoting health and wellness, as well as, reducing the incidence of preventable liver-related chronic diseases and lifestyles that negatively impact the liver. Some of these diseases include obesity, diabetes, hepatitis, substance abuse, HIV/AIDS, cardiovascular disease, fatty liver and liver cancer. We implement our mission through our touchstones to educate, prevent, serve, and support and reach well over 5 million patients and health care professionals annually.

HFI understands the importance of biosimilars for the treatment of various diseases, including hepatitis. We support the use of biosimilars and recognize that their use can be beneficial to the patient. As a patient advocacy organization, the patient and their quality of life must be protected first and foremost. For this reason, we believe that the naming of biosimilars should be as distinguishable as possible.

All medicines are assigned a nonproprietary name by which they can be identified and the naming conventions for biosimilars are still under development. In August 2015, FDA issued a draft naming guidance and proposed a framework for naming all biologics, including biosimilars. This proposal would assign a distinguishing suffix to all biologics, which would be attached to the core by a hyphen. This approach enables physicians to prescribe with specificity and assists to ensure that products are dispensed according to the intent of the doctor. Also important, the suffix is intended to facilitate accurately associating any drug problem with the correct medicine. Because copies of biologics will not be identical to the original product, the differences may be important for some patients. It is important for doctors to know which product the patient is reacting to. By convention, small molecular drugs and their generic formats share a nonproprietary name. The World Health Organization (WHO) assigns an International Nonproprietary Name (INN). Like many countries, the United States considers the INN but has its own naming conventions and issues each molecule a "USAN" - United States Assigned Name. These allow physicians to identify the chemical composition to better prescribe for their patients. It is important that guidelines for biosimilars are in place, because biosimilars are not structurally identical to the product they copy and those differences may matter to some patients.

Naming is an important aspect of drug development. Names are a form of the tracking process to link any adverse events or successes from clinical trials and post-surveillance observations. Given the vast differences between chemical compounds and biologics, biosimilars need to be given distinguishable non-proprietary names. By providing this information dating back to the point of prescriptions, distinguishable names facilitate tracking a biosimilar's success and/or

failure. By tracking the biosimilar, it is possible to effectively determine the cause of an adverse event by creating a direct route back to the origin of the problem. Issues that may arise for a specific biological product can be untraceable without distinguishable names. A distinguishable naming system is an important component of improving transparency in the health care arena.

Government regulatory policies of biosimilars will evolve based on the actual experiences derived from the patient population. This calls for a closer examination and monitoring of adverse events reported from clinical trials and post-market surveillance tracking data. This could be made easier to follow, if the naming of the biosimilars are specific enough.

It is for these reasons that HFI takes the stance that the best way to name biosimilars in a clear, distinguishable way is to add a suffix connected to the manufacturer of the biosimilar. It ensures transparency on the end of the manufacturer, as well as clarity for health care providers and patients. Using the specific suffixes, instead of a random series of letters, would make distinguishing between similar biologic products easier. If the biosimilar is to be created by a new manufacturer than the initial or considered to be interchangeable with its reference drug, we also take the position that the suffix not be changed in order to minimize confusion related to the biosimilar.

HFI hopes that the comments made in this letter will assist the FDA in making a decision that keeps the health and wellbeing of the patient in mind. We understand the difficult process of finalizing the guidance and hope the comments have made a difference.

We commend the FDA for its leadership on biologic naming and for promoting patient safety, pharmacovigilance, and improved knowledge on the best use of biosimilars. This Draft Guidance is a significant positive step toward achieving these goals in the U.S. and globally.

Thank you for allowing the Hepatitis Foundation International to comment on this critical issue.

Sincerely,

Ivonne Fuller Cameron
CEO, Hepatitis Foundation International