Bayer HealthCare

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Docket No. FDA–2013–D–1543

October 27, 2015

Dear Sir or Madam:

Bayer HealthCare LLC ("Bayer") is pleased to submit these comments in response to the Food and Drug Administration's ("FDA's") Federal Register notice issued on August 28, 2015, requesting comments on the FDA Draft Guidance entitled "Nonproprietary Naming of Biological Products."[1]

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Bayer is a U.S.-based division of Bayer AG, one of the world's leading, innovative companies in the healthcare and medical products industry. Bayer combines the activities of the Animal Health, Consumer Care, Medical Care, and Pharmaceuticals divisions. In the United States, Bayer HealthCare Pharmaceuticals comprises the following business units: Women's Healthcare, General Medicine, Hematology/Neurology and Oncology. With more than 6,000 healthcare employees across the United States, Bayer aims to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases. We focus our efforts where we can have the most beneficial impact on the lives of those who depend on over 150 years of experience researching and developing new pharmaceuticals and medical devices.

General Comments

Bayer is supportive of FDA's efforts in drafting this guidance to support distinguishable, unique nonproprietary names for all biological products. Such an effort will help ensure patient safety, and potentially decrease errors in regards to pharmacovigilance, ordering, prescribing, dispensing, recordkeeping and insurance claims.

Regarding the proposed use of a suffix to achieve this goal, Bayer believes that each licensed biological product should have a meaningful suffix, and the

[1] Fed. Reg. Vol. 80 No. 167, pp. 52296-52299

suffix attached to the non-proprietary name should be derived from the name of the license holder listed on the license. Additionally, this suffix would apply to each of the company's licensed products and apply to biosimilar and interchangeable products. Having the suffix refer to the license holder will facilitate FDA's goals of ensuring safe use, pharmacovigilance and consistent naming convention, as described below.

Safe Use

Biologics are complex, large molecules that present unique safety issues. As such, it is important to avoid inadvertent switching and to maintain a patient on the same medication of the licensed holder's biologic for safety reasons and continuity of care to a product when no interchangeable designation has been granted.

Healthcare professionals (HCPs) and some patients are familiar with company names. Thus, Bayer believes that using a license holder-derived name would facilitate recognition, understanding and memorability of the suffix for both HCPs and patients. The license holder-derived name would be less confusing and easier to remember for HCPs and patients, than a random four letter suffix which lacks meaning (e.g., -BAYR (for Bayer) compared to –VXQA (illustrative example)). The use of a random 4-letter suffix may introduce confusion, and lead to medication errors and, inadvertent substitution as well as hinder pharmacovigilance.

Importantly, there may be situations where one has the option to choose from multiple biosimilars and interchangeable products. In those instances, the license holder-derived suffix, as mentioned above, would be more recognizable to HCPs and patients, ensuring that patients consistently receive the same biologic, if medically indicated. Additionally, changes in the manufacturing process may cause drift between the reference product and the biosimilar or interchangeable product, thus, utilizing a distinguishable, unique nonproprietary name, such as the license holder derived suffix, will assure that proper detection of these issues and that the appropriate biologic will be identified.

Pharmacovigilance

Moreover, Bayer believes that utilization of shared nonproprietary name or a non-meaningful, random suffix could delay the identification of the correct biologic associated with an adverse event, and the subsequent analysis and detection of a safety signal for that biologic. The use of a license holder-derived suffix would be more immediately identifiable and less confusing than a random, meaningless suffix and may enhance pharmacovigilance (PV) of all biologics with the same non-proprietary name. Additionally, using the same license-holder derived name for all of a company's portfolio of biological products can assist in identifying wider quality and safety issues within a company (e.g., through Sentinel).

Consistent Naming Convention

In addition to providing a consistent, recognizable, and meaningful naming convention for all biological products (both 351(a) and 351 (k) approvals) that will help HCPs and patients to quickly and accurately identify the appropriate biological product. The license holder-derived suffix would also help avoid the misperception of safety and efficacy of a biologic

based upon the approval pathway, since it would not identify the approval pathway used for the biological product.

A naming convention that uses a suffix that is assigned to a license holder also provides for a more efficient use of the Agency's valuable resources. Under such a system, FDA would approve one suffix for each company, and once approved, there will be no need for FDA to go through the suffix approval process for the other biological products licensed by the same company, whether previously or newly approved. This naming convention would also reduce the regulatory burden on industry.

Change of BLA Ownership

In the event that a BLA changes ownership to another company (i.e. merger or selling of assets), Bayer believes that the new license holder would have the ability to submit a CBE labeling supplement with the company's suffix derived from the new license holder's name. If the new license holder does not already have an FDA-approved suffix, it would have the opportunity to propose a suffix composed of four lowercase letters derived from the new license holder's name, to be used as the distinguishing identifier included in the *proper name* designated by FDA at the time of licensure for this application and to be used for all subsequent BLAs.

We also submit for your consideration the following specific comments below.

Specific Comments

Specific Comments on Text		
Line Number	**Comments**	**Proposed Change**
272-273	Bayer believes that all biological products including interchangeable biological products should have a suffix that is derived from the license holder's name. Interchangeable biologics and their reference products should not have the same suffix.	Replace "For interchangeable products, FDA is considering whether the designated suffix should be unique or should be the same as the reference product" with "The suffix will be unique to the license holder, regardless of approval pathway for the biological product."
278-280	"A designated suffix composed of four lowercase letters will be added to the *core name* of each product and will be attached with a hyphen."	Replace with "A designated suffix composed of four lowercase letters derived from the license holder's name will be added to the *core name* of each product and will be attached with a hyphen."
285-305	The examples listed use meaningless four-letter suffixes.	Replace examples with suffixes derived from the license holder's name using fictional examples.
312-315	"An applicant for a biological product submitted under section 351(a) of the PHS Act should propose a suffix composed of four lowercase letters for use as the distinguishing identifier included in the	Replace with "If an applicant for a biological product submitted under section 351(a) of the PHS Act does not already have an FDA-approved suffix derived from the license holder's name,

	proper name designated by FDA at the time of licensure (see section V of this guidance)."	the applicant should propose a suffix composed of four lowercase letters derived from the license holder's name for use as the distinguishing identifier included in the *proper name* designated by FDA at the time of licensure for the application and will be used for all subsequent biological products (see section V of this guidance)."
317-326	Bayer believes that any company that currently owns the license to a specific biological product would have the ability to proactively propose a suffix composed of four lowercase letters derived from the license holder's name as the distinguishing identifier included in the *proper name of all currently licensed biological products licensed by the company.*	Add "Any company that currently markets biologics can proactively propose a suffix composed of four lowercase letters derived from the license holder's name for use as the distinguishing identifier included in the *proper name of all currently licensed biological products licensed by the company."*
330-333	"An applicant for a proposed biosimilar product submitted under section 351(k) of the PHS Act should propose a suffix composed of four lowercase letters for use as the distinguishing identifier included in the *proper name* designated by FDA at the time of licensure (see section V of this guidance)."	Replace with "If an applicant for a proposed biosimilar product submitted under section 351(k) of the PHS Act does not already have an FDA-approved suffix derived from the license holder's name, the applicant should propose a suffix composed of four lowercase letters derived from the license holder's name for use as the distinguishing identifier included in the *proper name* designated by FDA at the time of licensure for this application and will be used for all subsequent BLAs (see section V of this guidance).
339-350	Bayer believes that the suffix should be attributable to the license holder, and that each biological product should have its own distinct proper name.	Place a period after "….in an original application or supplement." and delete the text in lines 339-350. Replace lines 339-350 with "If an applicant for a proposed interchangeable product submitted in an original application under section 351(k) of the PHS Act, and the applicant does not already have an FDA-approved suffix derived from the license holder's name, the applicant would propose a unique suffix composed of four lowercase letters derived from the license holder's name for use as the distinguishing identifier included in the *proper name* designated by FDA at the time of licensure for this application and will be used for all subsequent BLAs (see section V of this guidance)."

358- 364	Bayer proposes utilizing a suffix derived from the license holder's name.	Replace with: "The license holder should propose a suffix derived from the license holder's name. The suffix should consist of four lowercase letters."
380	"Be too similar to any other product's suffix designation"	Replace with "Be too similar to any other license holder's suffix designation."
385-386	"FDA expects that a proposed suffix will be appended to the core name of each biological product"	Replace with "FDA expects that a proposed suffix will be appended to the core name of each biological product licensed by the company"
288-391	"If the naming convention is first applied to a new product, the request for FDA's review of the preferred suffix should occur during the investigational new drug application (IND) phase or at the time of BLA submission."	Replace with "If the naming convention is applied to a company's first biological product for licensure, the request for FDA's review of the preferred suffix derived from the license holder's name should occur during the investigational new drug application (IND) phase or at the time of the BLA submission."
391-392	"For BLA holders seeking to propose a distinguishing suffix after approval, FDA recommends that a prior-approval labeling supplement be submitted." If the company already has an approved suffix, the company should submit a CBE.	Add after "….prior-approval labeling supplement to be submitted." "For BLA holders who have an approved suffix, a CBE be submitted with the FDA approved suffix."
392	Add sentence on changing ownership of a BLA. Proposal to submit the proposed suffix for previously approved products as a bundled labeling supplement for all biological products held by that license holder. A proposal to submit a CBE labeling supplement for an approved product if a suffix has been approved for a new product. For example, if the suffix is approved during the review of a new biological product, the approved suffix can be added to previously approved products via CBE labeling supplement. Similarly, if the license is reissued to a new license holder, and if that license holder already has an approved suffix, the suffix can be changed via a CBE labeling supplement.	Add "In the event that a BLA changes ownership to another company (i.e. merger or selling of assets), the new license holder should propose a suffix composed of four lowercase letters derived from the new license holder's name for use as the distinguishing identifier included in the *proper name* designated by FDA at the time of licensure for this application and will be used for all subsequent BLAs." "If the company already has an approved suffix, a CBE labeling supplement should be submitted with the FDA approved suffix."

We thank you for your consideration of these comments. If you have any questions, please do not hesitate to contact me by phone at 862.404.4036 or via e-mail at todd.paporello@bayer.com.

Sincerely,

Todd Paporello

Digitally signed by Todd Paporello
DN: o=Bayer, ou=Email SignCert, 0.9.2342.19200300.100.1.1=828D536E03EC4F0AA9BC4DF058FB6348FA321A0C, cn=Todd Paporello
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