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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville MD 20852

Supplemental Submission to Citizen Petition 2013-P-2014-P-1398, submitted on October 28, 2013

The Novartis Group of companies (Novartis) proposed in Citizen Petition 2013-P-1398 that the FDA require a biosimilar to be identified by the same nonproprietary name (NPN) as the reference product.

A. Action Requested

With this submission, we are supplementing the above-referenced Citizen Petition by providing additional details of our proposed biosimilar naming solution. Our proposal advocates a unique name for all biologics and biosimilars while seeking to minimize changes to the current nonproprietary naming convention.

1. We continue to believe that requiring a proprietary name (also known as "brand name" or "trade name") for a biologic, including biosimilars, is the best way to ensure (1) traceability, (2) that only biosimilars designated as interchangeable can be substituted, and (3) ensure product safety. If a biosimilar is licensed with a proprietary name it should be assigned the same NPN as the reference product for the reasons articulated in the above-listed Citizen Petition.

2. Nonetheless, if a company elects to license a biosimilar without a proprietary name, the FDA should utilize the authority it has with respect to the NPN and patient safety and assign a unique NPN in which the NPN of the reference product is supplemented with a distinguishable suffix that is linked to the biosimilar sponsor so that it can be differentiated from the reference product.

We believe our proposal addresses the key concerns made by interested parties with respect to the naming of biosimilar products.

Since submission of the Citizen Petition, the FDA has approved the first biosimilar, Zarxio™ (filgrastim-sndz), manufactured by Sandoz, a Novartis company. However, the FDA has specified "filgrastim-sndz" as a "placeholder nonproprietary name" and said that this is not reflective of the agency's decision on a comprehensive naming policy for biosimilar and other biological products. FDA has however committed to issue a draft guidance on naming of current and future biological products marketed in the US.

The suggestion to add a distinguishable suffix to the NPN (which may also be the INN/USAN) of the reference product is based on theoretical concerns related in part to pharmacovigilance so that the originator and biosimilar can be differentiated in the event that product use is recorded by use of only the NPN, and not one of the many other identifiers that are already available and in use (e.g. NDC code, J-code, brand-name etc.). At the same time, the overwhelming consensus in the US is that it is important to clearly understand by means of naming that there is a relationship between a biosimilar and the reference product.

The format proposed by the placeholder NPN (e.g. "filgrastim-sndz") does make it clear that the biosimilar and reference product are linked, but at the same time it also introduces a host of other difficulties as described in the original Citizen Petition 2013-P-1398 such as new safety concerns and a probable public perception by some that a biosimilar is significantly different from the reference product despite meeting FDA's evidentiary threshold of "no clinically meaningful differences" with its reference product.

B. Impact on Products Already Approved

If one takes a position that an NPN+distinguishable suffix is necessary to avoid inadvertent interchangeability and to enhance pharmacovigilance, then it must follow that this can best be accomplished if BOTH the reference product and biosimilar have NPNs with distinguishable suffixes. As a result, the product name of the reference product will need to be modified when a biosimilar to that product is approved.

And if the need to prevent interchangeability of products that share the same NPN is indeed a newly identified safety concern, the public good requires that the FDA retroactively assign a new NPN+distinguishable suffix combination to the more than 40 biologics that have already been approved in the US and that already share the NPN with another FDA-approved product.

Of course, there are decades of experience in the US whereby biologics that have not been compared to each other nonetheless share the same NPN and have been safely prescribed, dispensed, and administered. To our knowledge, no safety concerns have been raised for these products related to naming, largely because these products have distinct proprietary names.

C. Clarified Proposal

Novartis and Sandoz are hereby clarifying our naming proposal for biosimilars to meet the desired objectives while avoiding concerns and difficulties that might be caused by the placeholder naming convention. It also avoids the need to consider renaming many previously licensed products.

- Other than supporting technologies that record current product labeling in patient charts or electronic medical records (e.g. barcode that contains the proprietary name, NPN, manufacturer, NDC number and batch number), a proprietary name is the best option (1) to ensure proper traceability of a biosimilar and (2) to help minimize inadvertent interchangeability that might be caused by naming confusion. As such, use of proprietary names for biosimilars should be strongly encouraged. Once a proprietary name is reviewed and approved by the FDA, the NPN of the biosimilar should be the same as that of the reference product.

- In the event that a sponsor requests licensure a biosimilar without a proprietary name, the FDA would utilize the authority it already has and assign a unique NPN consisting of the NPN of the reference product supplemented with a distinguishable suffix that is linked to the name of the biosimilar sponsor. Although not as desirable as a proprietary name, we appreciate the need to differentiate in some manner between reference product and biosimilar.

In selecting a distinguishable suffix that is linked to the biosimilar sponsor name, we believe that the full biosimilar sponsor name would more helpful than an abbreviated format because use of the full name avoids potential misunderstanding. However, we appreciate that some sponsors have long company names and that use of full company names as a distinguishable suffix may be impractical for those sponsors.

D. Advantages of this proposal include:

1. This proposed solution makes it clear that the biosimilar and its reference product are related, and that safety observations after administration of the reference product can be relevant to the biosimilar and *vice versa*.

2. The proposed solution avoids the need to revise the NPN of the reference product and perhaps to all biologics that have already been approved in the US. The biosimilar and reference product will have unique names, either as different proprietary names or different NPNs, as well as J-codes and different NDC numbers. Recording of NDC codes is mandatory for reimbursement when dispensed from a pharmacy and J-codes are mandatory for Medicare reimbursement.

3. There is no need to reconsider the current naming policy for originator biologics that will be approved in the future.

4. Novartis and Sandoz appreciate that the FDA cannot mandate use of proprietary names for either drugs or biologics. The biosimilar naming solution proposed here does not necessitate a change in statute or current policy. The proposed solution is consistent with optional use of proprietary names and these remain voluntary, but when used they will be subject to FDA oversight for clarity and distinguishability.

5. Notably, our recommendation is very similar to the naming policy that is being used successfully in European Union for biological drugs (including 21 biosimilars, including

multiple biosimilars to the same reference product) because EMA requires proprietary names while utilizing the same INN for a biosimilar and its reference product. There have been no reports of issues related to tracking and tracing of safety events of biologics (including biosimilars) in the European Union since the first biosimilars were approved there in 2006.

Respectfully submitted on behalf of the Novartis Group of Companies

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