Provisional Translation (as of December 2024)*

PFSB/ELD Notification No. 0214-1

February 14, 2013

To: Prefectural Health Department (Bureau)

From: Director, Evaluation and Licensing Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Handling of Non-proprietary Names and Brand Names related to Biosimilars

The title has been handled by the PFSB/ELD Notification No. 0304011 dated March 4, 2009 (hereinafter referred to as "old notification"). From the viewpoint of better clarifying the handling of simple protein drugs, we have revised the old notification in this case. Therefore, we hope that you will be aware of this issue, and inform manufacturers and sellers placed under your administration.

The old notification will be abolished in accordance with the implementation of this notification.

Note

The non-proprietary name and brand name of the biosimilars should be easily distinguishable from the name of the original biopharmaceutical and other biosimilars to clearly indicate that the product is a biosimilar.

Specifically, the non-proprietary name shall be the name determined in accordance with PFSB Notification No. 0331001 dated March 31, 2006 and PFSB/ELD Notification No. 0331001 dated the same date, and "biosimilar 1 (2, 3,...)" shall be added in square brackets to the end of the non-proprietary name of the original biopharmaceutical (excluding the description pertaining to genetical recombination) at the time when it is determined to be a biosimilar through the approval review of the individual product. However, for drugs for which the primary structure of the intended active ingredient of a simple protein drug is judged to be the same as the active ingredient of the original biopharmaceutical, the non-proprietary name shall be the name of the original biopharmaceutical, without adding a new non-proprietary name.

As for the brand name, it is in principle to follow the PFSB/ELD Notification No. 0922001 dated September 22, 2005, in which the dosage form, content, and company

name (house name, etc.) should be added to the non-proprietary name (omitting the description of genetical recombination, etc. in the name, and attaching "BS" instead of "biosimilar 1 (2, 3…)").

<Exemplary>
Non-proprietary name: ○○○○○ (Genetical Recombination) [×××××biosimilar 1]
Brand name: ×××××BS Injection Content Company name
(NOTE)The name of "○○○○○ (Genetical Recombination)" was established by PFSB Notification No. 0331001 dated March 31, 2006, from the Director-General of the Pharmaceutical and Food Safety Bureau.
The ×××××× denotes the non-proprietary name of the original biopharmaceutical, excluding "(genetical recombination)".

Before and after comparison table

New	Old
(Abbreviated) Specifically, the non-proprietary name shall be the name determined in accordance with PFSB Notification No. 0331001 dated March 31, 2006 and PFSB/ELD Notification No. 0331001 dated the same date, in which "biosimilar 1 (2, 3,...)" shall be added in square brackets to the end of the non-proprietary name of the original biopharmaceutical (excluding the description pertaining to genetical recombination) at the time when it is determined to be a biosimilar through the approval review of the individual product. However, for drugs for which the primary structure of the intended active ingredient of a simple protein drug is judged to be the same as the active ingredient of the original biopharmaceutical, the non-proprietary name shall be the name of the original biopharmaceutical, without adding a new non-proprietary name. （Omitted）	(Abbreviated) Specifically, the non-proprietary name shall be the name determined in accordance with PFSB Notification No. 0331001 dated March 31, 2006 and PFSB/ELD Notification No. 0331001 dated the same date, in which "biosimilar 1 (2, 3,...)" shall be added in square brackets to the end of the non-proprietary name of the original biopharmaceutical (excluding the description pertaining to genetical recombination) at the time when it is determined to be a biosimilar through the approval review of the individual product. However, for drugs (e.g., growth hormone, insulin, etc.) for which the primary structure of the intended active ingredient is judged to be the same as the active ingredient of the preceding biopharmaceutical, such as simple protein drugs, the non-proprietary name shall be the name of the original biopharmaceutical, without a new non-proprietary name as in the past. （Omitted）