

**English Translation (PFSB/ELD No.0304011) by PhRMA**

**PFSB/ELD No. 0304011  
March/4/2009**

**To: Directors, Health Bureaus, Prefectural Government**  
**From: Director, Evaluation and Licensing Division**  
**Pharmaceutical and Food Safety Bureau,**  
**Ministry of Health, Labor and Welfare.**  
**Re: Handling of nonproprietary and brand names of follow-on biologics**

The “Guidelines for the Quality, Safety and Efficacy Assurance of Follow-on Biologics” have been set out in PFSB/ELD No. **0304007**, dated March/4/2009. The nonproprietary and brand names for follow-on biologics under these guidelines shall be as follows, of which, with your acknowledgment, we request you to ensure that the parties concerned under your authority are advised.

**Notice**

To specify clearly that a drug is a follow-on biologic, the nonproprietary names and brand names of follow-on biologics should be readily distinguishable from the nomenclature of originator biodrugs and other follow-on biologics.

Specifically, for nonproprietary names given in accordance with PFSB No. 0331001, Notification from the Director-General, Pharmaceutical and Food Safety Bureau dated March 31 2006 and our Notification PFSB/ELD No. 0331001 of the same date, “Follow-on 1 (2, 3,...)” should be suffixed to the nonproprietary name of the originator biologic (excluding recombinant descriptions) at the time the individual product is determined to be a follow-on biologic through approval review thereof. Nonproprietary names that have been reviewed shall, after reporting to the forum for expert deliberation of drug nomenclature at the Pharmaceuticals and Medical Devices Agency, be notified separately.

For brand names, in accordance with PFSB/ELD Notification No. 0922001 dated September 22 2005, in principle the dosage form, dosage and company name (business name etc.) should be attached to the nonproprietary name (omitting “recombinant” etc. and stating “BS” instead of “Follow-on 1 (2, 3,...)”).

**Examples**

**Nonproprietary name:** OOOOOO (Recombinant) [ XXXXXX Follow-on 1]

**Brand name:** XXXXXX BS Injectable Content Company Name

Note: “OOOOOO (Recombinant)” is the nomenclature specified pursuant to PFSB No. 0331001, Notification from the Director-General, Pharmaceutical and Food Safety Bureau dated March 31 2006 and other notifications.

“XXXXXX” excludes “recombinant” from the nonproprietary name of the originator biodrug