事　務　連　絡
平成 26 年 4 月 9 日

各都道府県衛生主管部（局）薬務主管課　御中

厚生労働省医薬食品局審査管理課

後発医薬品の生物学的同等性試験ガイドライン等の英文版の一部訂正について

平成 24 年 9 月 10 日付け事務連絡「後発医薬品の生物学的同等性試験ガイドライン等の英文版について」において、一部誤りがあったので、別添のとおり訂正方よろしくお願いいたします。

別　添

Guideline for Bioequivalence Studies of Generic Products（後発医薬品の生物学的同等性試験ガイドライン）

訂正前	訂正後
Section 3: Tests （略） **B. Oral extended release products** （略） **II. Bioequivalence studies** **1. Test Method** Bioequivalence studies should be performed by single dose studies in both the fasted and fed states. In the case of postprandial administration, a high fat diet of 900 kcal or more containing 35% lipid content should be used. The meal should be eaten within 20 min, and drugs administered within 10 min thereafter. When a high incidence of severe adverse events is indicated after dosing in the fasting state, the fasting dose studies can be replaced with postprandial dose studies with the low fat meal employed in the study for oral immediate release products and enteric-coated products. Other testing conditions should follow those of oral immediate release products and enteric-coated products. （略）	**Section 3: Tests** （略） **B. Oral extended release products** （略） **II. Bioequivalence studies** **1. Test Method** Bioequivalence studies should be performed by single dose studies in both the fasted and fed states. In the fed study, a high fat diet of 900 kcal or more and calories from fat exceeding more than 35% of total calories. The meal should be eaten within 20 min, and drugs administered within 10 min thereafter. When a high incidence of severe adverse events is indicated after dosing in the fasting state, the fasting dose studies can be replaced with postprandial dose studies with the low fat meal employed in the study for oral immediate release products and enteric-coated products. Other testing conditions should follow those of oral immediate release products and enteric-coated products. （略）