Provisional Translation (as of October 2021)*

Administrative Notice
September 14, 2021

To: Pharmaceutical Administration Section, Health Departments (Bureaus),
Prefectural Governments

Pharmaceutical Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

English Translations of Guidelines for Bioequivalence Studies of Generic Products

The Guidelines for Bioequivalence Studies of Generic Products and related Questions and Answers (hereinafter referred to as "the guidelines") have been amended by the following Notification and Administrative Notice.

"Partial Revision of the Guidelines for Bioequivalence Studies of Generic Products" (PSEHB/PED Notification No. 0319-1 dated March 19, 2020)

"Revision of the 'Questions and Answers (Q&A) on the Guidelines for Bioequivalence Studies of Generic Products'" (Administrative Notice dated March 19, 2020).

The guidelines have been translated into English and announced recently in the "Research on Development of Bioequivalence Assessment Methods for Prescription Drugs and Preparation of Draft Guidelines" (Chief Researcher: Hiroyuki Yoshida, Head of First Section, Division of Drugs, National Institute of Health Sciences. FYs 2019-2021 Medical Research and Development Grants by the Japan Agency for Medical Research and Development [AMED] for Research on Regulatory Science of Pharmaceuticals and Medical Devices). The English translations are publicly available on the website of National Institute of Health Sciences at the following URL. We ask you to inform manufacturers and sellers placed under your administration about the English translations of the guidelines.

URL for the guidelines: https://www.nihs.go.jp/drug/index-E.html#BE

∗ This English version of the Japanese Administrative Notice is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.