

(Attachment)

Designation of “Shitei Yakubutsu” (designated substances) based on the provision of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (1960, Law No.145)

In order to clarify the regulation under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (hereinafter referred to as the “Act”), the Minister of Health, Labour and Welfare of Japan proposes to designate the following substances as “Shitei Yakubutsu” (designated substances). Manufacture, import, sale, simple ownership and the use of “designated substances” are banned except for the “proper uses” (see below).

- The proposed substances as “Shitei Yakubutsu”
 - ※Abbreviation is put in parentheses.
 - 1. 2-[(4-Chloro-2,5-dimethoxyphenethylamino)methyl]phenol (25C-NBOH)
 - 2. 1-(4-Fluorobenzyl)-N-(naphthalen-1-yl)-1H-indole-3-carboxamide (FDU-NNE1)
 - 3. 2-(4-Iodo-2,5-dimethoxyphenyl)-N-(3,4-methylenedioxybenzyl)ethanamine (25I-NB34MD)

- The “proper uses” for all “Shitei Yakubutsu”, designated based on the Act
 - 1. To be used for researches or tests at the government, the local governments, agencies thereof, technical colleges, inter-university research institutes, the independent administrative agencies and the local independent administrative agencies
 - 2. To be used for tests under the Act, and
 - 3. To be used for forensic use