<u>Designation of Shitei Yakubutsu</u> (designated substances) based on the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (1960, Law No.145)

In order to prevent the abuse of substances with probable effects on the central nervous system and to clarify the regulation under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the Act), the Minister of Health, Labour and Welfare of Japan proposes to additionally 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.

3 substances

1. N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-benzyl-1H-indazole-3-carboxamide

[ADB-BINACA]

2. 2-(Ethylamino)-2-(3-fluorophenyl)cyclohexanone [FXE, Fluorexetamine]

3. 2-(Butylamino)-1-(3,4-methylenedioxyphenyl)butan-1-one [N-Butylbutylone]

2 substance groups

1. Any compounds in which a linear alkyl group (the number of carbon atoms is limited from 3 to 8) is bonded to the 3-position and no further substituents are attached other than at the 1-, 3-, 6-, and 9-positions of 6a,7,8,10a-tetrahydro-6,6,9-trimethyl-6*H*-dibenzo[*b*,*d*]pyran-1-ol, and salts of these compounds. Except in the case of narcotics as defined in the Narcotics and Psychotropics Control Law.

OH

R

$$R = n-C_3H_7, n-C_4H_9, n-C_5H_{11}^*, n-C_6H_{13}, n-C_7H_{15}, n-C_8H_{17}$$

* $n-C_5H_{11}$: Narcotic (Δ^9 -THC)

2. Any compounds in which a linear alkyl group (the number of carbon atoms is limited from 3 to 8) is bonded to the 3-position and no further substituents are attached other than at the 1-, 3-, 6-, and 9-positions of 6a,7,10,10a-tetrahydro-6,6,9-trimethyl-6*H*-dibenzo[*b*,*d*]pyran-1-ol, and salts of these compounds. Except in the case of narcotics as defined in the Narcotics and Psychotropics Control Law.

R= n-C₃H₇, n-C₄H₉, n-C₅H₁₁**, n-C₆H₁₃, n-C₇H₁₅, n-C₈H₁₇
**n-C₅H₁₁: Narcotic (Δ ⁸-THC)

- The proposed proper uses for the above *Shitei Yakubutsu* are;
- 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