Public summary of the dossier: Synthetic Cannabidiol (CBD).

Applicant: Farmabios S.p.A. Via Pavia, 1 - 27027 Gropello Cairoli, (PV), Italy.

This application for authorisation of a novel food in accordance with Regulation (EU) 2015/2283 concerns a white or almost white, crystalline powder (98.0%- 102.0%) CBD, obtained by chemical synthesis, and produce under strictly controlled EU-GMP conditions.

All the specifications of Synthetic CBD are detailed in this application and are in accordance with European standard and regulations.

The production process is fully described. Description of chemical synthesis and information on the multi-step process conditions are given. The identity of the ingredient is well characterised, as demonstrated by analyses using a variety of analytical methods including infrared spectroscopy, nuclear magnetic resonance spectroscopy, mass spectrometry and ultraviolet–visible spectroscopy. Analysis of several independent, representative batches of CBD demonstrates that the manufacturing process produces a consistent ingredient, which complies with the establish specifications. Full stability data program is provided, in accordance with ICH guideline.

Analyses have demonstrated high purity with the lack of contaminants, including those related to a synthetically produced purified compound.

In accordance with proprietary data, literature and authorities opinions, Farmabios synthetic CBD will be used in food supplements and other various food categories within the limit dose recommended by the Food Standards Agency (FSA), i.e. the healthy adults do not take more than 0.17 mg/kg BW/day (4 mg/day in a 70-kg adult) has been proposed as safe dose in UK instead of 70 mg a day previously (1 mg/kg/day), and would not be nutritionally disadvantageous under the proposed conditions of use in food supplements. It is not intended to replace other foods. It is intended for consumption by adults in the general population, but not vulnerable groups i.e. children, pregnant and breastfeeding women, people taking any medication.

About allergenicity, a full analytical test was conducted. The nutritional profile of Synthetic CBD confirm its purity and with its absence of protein it is unlikely to be allergenic, in line with substantiated absence of any reports of allergenicity to CBD in any of the numerous human studies conducted with other forms of CBD.

The overall safety of Farmabios Synthetic CBD is supported by proprietary data and toxicological appraisal commissioned by the applicant, in accordance with a tiered approach considering the significant literature on CBD toxicology, recently reviewed by internationally acknowledged authorities. The applicant Farmabios performed its own genotoxicity tests on the Synthetic CBD, -conducted following OECD guidelines and GLP-, showing no reverse mutation and micronucleus cell alterations, and filling the gap on non-available genotoxicity data on CBD. In addition to this, over 120 studies in healthy volunteers or patients, children or adults, show CBD is largely used orally in Human with no serious adverse effects or, where reported, as a result of drug-drug interactions between CBD and patients' existing medication, to conclude that CBD is generally well tolerated with a good safety profile. In addition to this, literature on CBD pharmacokinetics and toxicokinetic parameters (T1/2, AUC, bioavailability, Cmax and Tmax) are clearly given, reviewed by internationally acknowledged authorities.

In conclusion, Synthetic CBD is well characterized and compliant with European Regulations. The product is safe and devoid of allergic potential. Synthetic CBD does not present consequently any potential hazard to the European population.