

Summary of the application: Natural Pure Cannabidiol

Applicant: Linnea SA, Via Cantonale, CH-6595 Riazzino (TI), Switzerland.

This application for authorisation of a novel food in accordance with Regulation (EU) 2015/2283 concerns a white/off-white or slightly yellow powder of purified CBD 98-102%.

In accordance with literature and authorities opinions, Linnea CBD will be used in food supplements within the limit dose recommended by the United Kingdom Food Standards Agency (FSA), i.e. the healthy adults do not take more than 70 mg a day (1 mg/kg/day) of CBD, and would not be nutritionally disadvantageous under the proposed conditions of use in food supplements. The novel food is not intended to replace other foods. It is intended for consumption by adults in the general population, but, due to the absence of specific data, the novel food is not intended for vulnerable groups i.e. pregnant and breastfeeding women, children, and people taking any medication.

All the specifications of pure CBD are detailed in this application and are in accordance with European standard and regulations. Analyses on 3 representative batches of pure CBD chemical substance that have been independently produced have demonstrated 1) the novel food is conformed to its specifications, 2) there is no variability from batch to batch and 3) the novel food is devoid of any contaminant (microbiology, residual solvent, heavy metals...). The production process is fully described and quality certifications covering manufacturing and testing of CBD are given with the GMP and ISO certifications. Stability and degradation are given on 3 batches of pure CBD. For each testing method, full description and validation of procedures are provided.

Literature on CBD pharmacokinetics is huge and toxicokinetic parameters ($T_{1/2}$, AUC, bioavailability, C_{max} and T_{max}) are clearly given and have recently been reviewed by internationally acknowledged authorities. Literature on CBD toxicology is huge and has recently been reviewed by internationally acknowledged authorities. More than 120 studies in healthy volunteers or patients, children or adults, show CBD is already largely used orally in Human with no serious adverse effects and at doses very above 1 mg/kg/d (70 mg/d CBD) as proposed for the Linnea CBD. CBD is generally well tolerated with a good safety profile. Reported adverse effects may be as a result of drug-drug interactions between CBD and patients' existing medications. About allergenicity, the nutritional profile of CBD shows absence of protein and literature already shows CBD is unlikely to be allergenic.

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