

Summary of the application: *Cannabis sativa* L. extract

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 dark green viscous liquid, produced from *Cannabis sativa* L. aerial part and standardized to 5% CBD (CM5). In accordance with proprietary data, literature and authorities opinions, Linnea CM5 will be used in food supplements at levels not exceeding 70 mg a day (1 mg/kg/day) of CBD (i.e. equivalent to 1.4 g of CM5) which has been proposed as safe dose in UK, 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 CM5 are detailed in this application and are in accordance with European standards and regulations. Analyses on 5 representative batches of CM5 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 CM5 are given with the GMP and ISO certifications. Stability and degradation are given on 7 batches of CM5. For every testing methods, full description and validation of procedures are provided.

The overall absorption, distribution, metabolism, and excretion profile of Linnea CM5 is given with a proprietary clinical study supported by literature that is huge on CBD pharmacokinetics 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.

The overall safety of Linnea CM5 (100 mg/d CBD) is substantiated by a proprietary clinical study and by the huge CBD toxicology database that 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 humans with no serious adverse effects and at doses very above 1 mg/kg/d (70 mg/d CBD) as proposed for the Linnea CM5.

CBD is generally well tolerated and 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 CM5 shows absence of protein and literature already shows CBD is unlikely to be allergenic.

In conclusion, CM5 is well characterized and compliant with European Regulations. The product is safe and devoid of allergic potential. CM5 does not present consequently any potential hazard to the European population.