

CiiTECH gets CBD ducks in a row for Novel Foods deadline

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CiiTECH is to switch to TTS Pharma for the supply of cannabidiol (CBD) for its UK brands in preparation for the Food Standards Agency's impending Novel Foods deadline.

UK-Israeli company CiiTECH has introduced five new CBD oils into its UK supply chain to ensure that its flagship Provacan and Impact sports ranges are compliant with the Novel Food regulations that enter into force in 2021.

From 31 March 2021, all CBD finished products on the UK market must have aligned themselves with a Novel Food application submitted to both the European Food Safety Authority (EFSA) and the Food Standards Agency (FSA).

The five new tincture products, which have a CBD concentration ranging from 3-15%, are all supplied by TTS Pharma, a UK based developer and manufacturer of hemp-derived products.

CiiTECH's decision to switch was grounded in TTS Pharma's status as the first UK company to submit its Novel Food dossier to the EC and establish an EU compliant supply chain.

"For the UK, there was a need to expedite our move towards ensuring our products are Novel Food compliant. Currently, we believe that TTS will be the first to secure the all important 'validated submission' in time for 31st March," Clifton Flack, founder and CEO of CiiTECH, told Nutraingredients.

CiiTECH confirmed that its current supplier will continue to produce Provacan for its customers and distribution partners outside Novel Food governed markets.

"We work with a number of suppliers across all our brands. Because we don't own our own facilities, we build relationships with suppliers based on their ability to create versions of our products for local markets according to consumer needs and regulations," said Flack.

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Dossiers under review

In December 2019, TTS Pharma became the first UK company to file a Novel Food dossier (2019/1458) with the EC. Four months after the dossier was submitted, the FSA responded with feedback. After a further three months, the EFSA responded but then suspended all reviews until the non-narcotic status of CBD was established in court in November 2020.

Clarifying the current status of the dossier, TTS Pharma's CEO Mark Tucker told this publication: *"We have accommodated both sets of recommendations and have split our dossier into two separate dossiers for distillates and isolates as requested. These will be re-submitted imminently with an expectation that the validation will be issued by the FSA during Q1 2021 and the EFSA some time later."*

In the meantime, TTS Pharma has been given 'Assured Advice' by the UK authorities to place its CBD onto the UK market; such consent guarantees its customers and their products statutory protection in the event of enforcement activities.

The products TTS Pharma supplies to CiiTECH are purified CBD oils with full terpene profiles. Derived from European hemp *Cannabis Sativa*, the company's CBD is said to be of the purest form, proven to be free from both CBN (Cannabinol) and THC (delta-9-tetrahydrocannabinol, THC-A and THC-V). An affiliate manufacturer, Ilesol Pharmaceuticals in Varazdin, Croatia, produces these products exclusively for TTS.

Opaque industry practices

The traceability and transparency of TTS Pharma's European supply chain was a key factor in CiiTECH's decision, according to Flack: *We're fundamentally confident that the TTS Pharma team have a significant advantage in quality compliance and provenance on the market,"* he said.

TTS Pharma captures and tracks data from the point of harvest all the way through to sale – a practice that it claims is *"commonplace in pharmaceuticals but noticeably absent in this industry"*.

"Therefore consumers don't know where their product is grown, who processed it or what the specification might be," said Tucker.

He continued: *"No consumer products are legally manufactured in the UK, due to the lack of licences issued by the Home Office to manufacture or work with distillates – only GW Pharma holds appropriate licensing. Everything has been imported either in bulk or finished product form and a significant proportion is illegal under current regulations. There are several firms who have wilfully acted unlawfully in doing so and to protect themselves they are not transparent as to the origin of their product or who handles it."*

Tucker said that many finished products that originate from outside Europe are derived from GMO hemp, hybridised hemp (mixed with cannabis) or cannabis itself as the yields are much higher compared to ordinary industrial hemp found on the EU Approved list.

"The end consumer does not know this and the sellers can't tell them because it is illegal – and once the biomass is processed it is difficult to distinguish between cannabis and hemp," he explained.

The hope is that the Novel Foods system will erase some of the inequity that exists in this market.

"Novel food is creating a paradigm shift in the industry. If the process rolls out as the FSA is planning then many compounds found in existing full plant extract CBD products will unlikely attain Novel Food approval status," said Flack.

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