BEWARE THE FALSE RACE FOR SUBMISSION (AND EVEN FOR VALIDATION)

The race for earliest submission of a Novel Food Dossier is a false one. This is especially the case when submissions made thus far, so we understand, lack the appropriate scientific data in respect of end products for which Authorisation is being contended and, in some cases, lack any scientific data in respect of the subject of the application at all.

What we are seeing at present are the early stages of a "Client Grab" by manufacturers of CBD Isolate and Delivery Technology, in which their aim is to increase their respective client bases – not to compile and/or submit an Authorisation-compliant dossier.

Manufacturers of end products who fail to undertake the necessary Due Diligence will, in due course, find themselves "painted into a corner" and faced with the choice of buying "pure White Label" products from those same manufacturers (who will by then, i.e. 31st March 2021, have been misleading them for a year), or selling goods which do not benefit from the UK FSA exemption and which will be liable to enforcement action.

THE NOVEL FOOD ISSUE

The sale of CBD products in all EU Member States is prohibited unless the product has been Authorised for sale following a risk assessment conducted under the Novel Foods procedure. However, the UK Food Standards Agency (UK FSA) has created a "window of opportunity" for products to be sold in the UK without a risk assessment under the Novel Food process having been completed.

What is required under the FSA scheme is that a product manufacturer must submit a Novel Food application and have it "Validated" by the 31st March 2021. If that is done, the product will be able to be lawfully sold in the UK throughout the whole period that the risk assessment is conducted by the UK FSA – which is likely to be a period of 2-3 years.

Thus, one can see that the Validation of an application by 31st March 2021 is hugely significant to someone who is seeking to sell compliant products to the UK market:

- achieve the Validation of a submission by 31st March 2021 and you will be able to sell and profit from your product until at least 2023 (and probably 2024), even if that product was (for whatever reason) considered unsuitable for authorisation at the end of the process; or,

- fail to achieve the Validation of a submission by 31st March 2021 and you will not be able to sell and profit from your product until at least 2023 (and probably 2024), only after it has been fully authorised.

In the former situation, income can be received to defray the expenditure incurred in the creation of the Novel Food application immediately. In contrast, in the latter situation there will be a 2-3 year delay in receiving any income, despite having been required to make the investment in the product and the application immediately.

Thus, achieving the Validation of a Novel Food application by 31st March 2021 may be, for many, the difference between being able to offer a compliant product to the market and never being able to offer such a product because of the impact of the differential on:

- investment rate of return;
- the period of investment; and,
- an immediate income stream versus no income stream for 3 years.

APPLICATIONS ARE REQUIRED FOR THE ISOLATE, ANY "DELIVERY TECHNOLOGY" AND THE PRODUCT

There are a number of documents which outline the Novel Food application process in the Novel Food section of our website (https://www.thecannaconsultants.co.uk/novel-food-applications/). We would encourage market participants to read this material because in doing so you will further appreciate the importance of a product manufacturer:

- utilising an isolate manufacturer who is making a Novel Food application in respect of their isolate; and,
- utilising a delivery technology manufacturer (e.g. of an emulsion) who is making a Novel Food application in respect of their technology as it is applied to the Isolate; and,
- utilising a manufacturer of isolate and/or the Delivery Technology who will authorise your use of their underlying data in order to enable you to make a Novel Food application extension for your final product, predicated as it will be on their fundamental application.

A product manufacturer who utilises an Isolate supplier who does not achieve the Validation of a Novel Food application by 31st March 2021 will mean that the end product which uses that isolate will not be permitted for sale.

A product manufacturer who utilises a Delivery Technology supplier who does not achieve the Validation of a Novel Food application by 31st March 2021 will mean that the end product which uses that isolate and delivery technology will not be permitted for sale.

Thus, notwithstanding one's own conduct, one can see how imperative it is to be utilising a supply-chain which intends to be:

- Novel Food compliant in principle; and,

- Novel Food compliant in terms of the UK FSA's requirements in order to ensure the ability to monetise your product and investment during the whole of the risk assessment process, rather than being positively prohibited from doing so until the final conclusion of the process.

In addition to the Isolate manufacturer and/or Delivery Technology making their applications own Novel Food authorisation, you <u>as a product manufacturer</u> will need to make an application for your product (which can be an extension to the manufacturer's application).

<u>NOT ALL NOVEL FOOD APPLICATIONS WILL BE EQUAL</u>

It is evident to us, despite the information being available if people wish to access it, that not all applications for Novel Food authorisation will be equal.

Primary market participants, by which we mean those who supply Isolates and/or Delivery Technology, are presently making statements which are inaccurate and misleading. The statements are either intentionally misleading or negligently so and appear, to us at least, to be made with the intent to secure a greater market share in the short-term, to the huge detriment of end-product clients in the longer-term.

Applications submitted ***without the necessary scientific studies at all***, or ***without the studies on the specific end product*** (as opposed to "CBD in general") are bound to failure. We say "huge detriment to the client", rather than the suppliers themselves, because those who make these statements will no doubt ensure that, in the end, they submit data for their own end products which they "White Label". They will then leave their clients with the choice of "buy our compliant white label product or buy an isolate that you can use to manufacture, but only to create products which you can't sell".

DUE DILIGENCE

In the light of the critical importance of utilising a Novel Food-compliant supply-chain we cannot over-stress the need for product manufacturers to establish to their satisfaction that the supplier of their CBD Isolate, including any Delivery Technology applied to it:

(a) intends to make Novel Food applications for the products with which you are supplied;

(b) confirms that you will be permitted to rely upon their underlying data in order to support an extension application for your products;

(c) identifies to you the internal department or external entity who will be responsible for the design, management and delivery of the Novel Food applications;

(d) provides you with the contact details of the head of that department/entity in order that you have a direct line of communication with them (and assess their competence); and,

(e) provides you with a timescale within which they intend to begin the work required for such applications.

In our view, unless you are provided with satisfactory answers to each of these questions, you should review whether you wish to continue your current commitment to utilising active supply-chain ingredients which will result in your products being illegal in the UK after 31st March 2021.

Beware of any manufacturer who tells you that their single application will cover all products, of all varieties (e.g. supplements, edibles, condiments and sweeteners, sports proteins, beverages, snacks and desserts to name but a few). It is necessary to undertake ADME studies of the end products being fed to rodents in the format that it will be ingested by a human. No isolate manufacturer will be undertaking the necessary testing which will cover all of these categories for all of the multitude of products which are encompassed by them.

If you conclude that it will be necessary for you to seek a new supplier of your active ingredients, then please let us know and we will be able to work with you in order to ensure of smooth transition to a new supplier, with minimal impact upon the current availability of your products and the maximum advantage to your application for Novel Food Authorisation.

Remember: Be Very Careful Who You Listen To