



**FINAL DETERMINATIONS MADE IN ACCORDANCE WITH REGULATION  
3A OF THE MEDICINES FOR HUMAN USE (MARKETING  
AUTHORISATIONS ETC.) REGULATIONS 1994 AS AMENDED.**

**VOLUME 5**

(From January 2016)

This document provides a list of Final Determinations issued by the Borderline Section on behalf of the Licensing Authority of the United Kingdom. Details of the product names, the names of the companies to whom the determination notices were issued and brief details of the reasons for the determination are provided.

A number of the determinations have been made after taking into account advice by the Independent Review Panel for Borderline Products and where applicable their advice is shown in the individual entry.

It should be noted that determinations are made on the basis of a product status at the time it was investigated. In some cases products will continue to be marketed in the UK having made appropriate modifications to ingredients and/or product presentation, to bring them into line with the Regulations, or because they were determined not be medicines.

A list of the determinations is given on the next page, ahead of individual entries for each product. Products are shown in the order that the determinations notices were issued.

All new entries to this document are shown in Red.

(Last Amended March 2019)

PRODUCT	COMPANY
1. Zestlife Saw Palmetto	Zestlife Ltd
2. Black Cohosh Tablets (200mg)	Simply Supplements
3. Ortisan Fruits and Fibres Regular Cubes	Laboratoires ORTIS sprl
4. NHP Agnus Castus Support	The Natural Health Practice Ltd
5. NHP Black Cohosh Nutrition Support	“ “ “
6. Echinacea Vegetable Capsules	Solgar UK
7. Zipvit Prosta-Plus	ZipVit Ltd
8. ZipVit Milk Thistle 3000mg tablets	“ “
9. Premium Natural Organic Hemp Flower Buds In Compressed Pellets – 100g	CBDO.co.uk
10. Organic Hemp Tea Bags	“ “
11. Organic CBD E-Liquid For Vaping	“ “
12. Organic CBD Oil – 10ml	“ “
13. Organic Water Soluble CBD Drops	“ “
14. Complete Joint Restore	Bulk Powders
15. Mobilise	“ “

<p><b>1</b></p>	<p>Product Name</p> <p>Company to whom notice was issued</p> <p>Date of notice</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Zestlife Saw Palmetto</p> <p>Zestlife Ltd</p> <p>14 January 2016</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product.</p> <p><u>The first limb</u> was satisfied due to wide public familiarity of the herb Saw palmetto and its associated uses in medicine, particularly for treatment of benign prostatic hyperplasia (BPH).</p> <p><u>The second limb</u> of the definition of a medicinal product was satisfied due to extensively available and published scientific data which has demonstrated this herb's ability to modify physiology through pharmacological means at the dosage level used.</p>
<p><b>2</b></p>	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Simply Supplements Black Cohosh Tablets (200mg)</p> <p>Simply Supplements</p> <p>3 February 2016</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product.</p> <p><u>The first limb</u> was satisfied due to wide public familiarity of the herb, which is associated with long-standing use within the herbal tradition, in particular for the treatment of adverse menopausal symptoms. Additionally, the company published a number of testimonials that referred to the beneficial effect in the relief of unwanted menopausal symptoms.</p> <p><u>The second limb</u> of the definition of a medicinal product was satisfied due to extensively available and published scientific data which has demonstrated this herb's ability to modify physiology through pharmacological means.</p>
<p><b>3</b></p>	<p>Product Name</p> <p>Company to whom notice was issued</p> <p>Date of notice</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Ortisan Fruits and Fibres Regular Cubes</p> <p>Laboratoires ORTIS sprl</p> <p>8 March 2016</p> <p>The product falls within both limbs of the definition of a medicinal product.</p> <p>The product fell within both limbs of the definition of a medicinal product.</p>

		<p><u>The first limb</u> was satisfied due to wide public familiarity of the herb. In addition the product was presented with claims including “help to promote regular bowel movements”, “a natural solution to an age old problem”, “a tasty way of gaining effective natural relief”, and “If you haven’t been for days and you’re feeling all bunged up”.</p> <p><u>The second limb</u> of the definition of a medicinal product was satisfied due to the inclusion of an active level of the herb <i>Cassia angustifolia</i> (Senna) in the product. Due to extensively available and published scientific data available for Senna, along with its availability in a number of authorised medicinal products, its pharmacological effect was undoubted and it was clear what effect consuming the product would have.</p> <p>The product is not a food supplement and would not form part of a healthy diet but would be used to obtain relief from constipation which is regarded to be an adverse medical condition</p>
4	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority’s Determination and reasons</p>	<p>NHP Agnus Castus Support</p> <p>The Natural Health Practice Ltd</p> <p>13 June 2016</p> <p>The product is a medicine under both limbs of the definition.</p> <p>The product fell within both limbs of the definition of a medicinal product.</p> <p>The first limb was satisfied due to claims for the treatment of premenstrual syndrome (PMS) and its associated adverse symptoms, both for the product as a whole and in the descriptions of its individual ingredients.</p> <p>The second limb of the definition of a medicinal product was satisfied due to the inclusion of the herbs Vitex Agnus castus and Black cohosh, both of which are extensively available and for which published scientific data which has demonstrated the ability to modify physiology through pharmacological means.</p>
5	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority’s Determination and reasons</p>	<p>NHP Black Cohosh Nutrition Support</p> <p>The Natural Health Practice Ltd</p> <p>13 June 2016</p> <p>The product is a medicine under both limbs of the definition.</p> <p>The product fell within both limbs of the definition of a medicinal product.</p> <p>The first limb was satisfied due to claims for the treatment of the associated adverse symptoms of the menopause, both for the product as a whole and in the descriptions of its individual ingredients.</p>

		<p>The second limb of the definition of a medicinal product was satisfied due to the inclusion of the herbs Vitex Agnus castus and Black cohosh, both of which are extensively available and for which published scientific data which has demonstrated the ability to modify physiology through pharmacological means.</p>
6	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Echinacea Vegetable Capsules</p> <p>Solgar UK</p> <p>30 January 2017</p> <p>The product is a medicine under both limbs of the definition.</p> <p>The product fell within both limbs of the definition of a medicinal product.</p> <p>The first limb was satisfied irrespective of an absence of medicinal claims, because the product would be perceived by the averagely well informed consumer as a medicinal product due to its well-known medicinal effects and long standing use in herbal medicine. Echinacea is not considered to be a food or to form part of a healthy diet. It would not be purchased by somebody other than to assist in respect of certain symptoms or illnesses, such as the common cold or flu.</p> <p>The second limb of the definition of a medicinal product was satisfied due to the inclusion of the herb Echinacea. There is a body of evidence of the physiological effects of Echinacea products in the treatment and prevention of the common cold, influenza and upper respiratory tract infections. A number of medicinal products containing Echinacea have been licensed or registered in the UK.</p>
7	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Zipvit Prosta-Plus</p> <p>Zipvit Ltd</p> <p>20 March 2017</p> <p>N/A</p> <p>The product fell within the first limb of the definition of a medicinal product.</p> <p>The first limb was satisfied because the product would be perceived by the averagely well informed consumer as a medicinal product due to the well-known medicinal effects and long standing use of Saw palmetto in herbal medicine. It is not a food supplement. In addition the product name gave the clear indication that the product was intended for the treatment of prostate related medical conditions in the male. This was reinforced by testimonials which were posted by men and referred to urinary problems.</p> <p>This is consistent with the determination made for a similar product named "Prostex".</p>

8	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Zipvit Milk Thistle 3000mg Tablets</p> <p>Zipvit Ltd</p> <p>8 December 2017</p> <p>N/A</p> <p>The product fell within the first limb of the definition of a medicinal product.</p> <p>The first limb was satisfied because the product would be perceived by the averagely well informed consumer as a medicinal product due to the well-known medicinal effects and long standing use of Milk thistle in herbal medicine. It is not a food supplement. This was reinforced by published testimonials which referred to the product being useful for liver problems and for treating "symptoms of over-indulgence".</p>
9	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Premium Natural Organic Hemp Flower</p> <p>CBDO.co.uk</p> <p>11 October 2018</p> <p>N/A</p> <p>The product satisfied the first limb of the definition. The product was presented for the treatment of a wide range or serious adverse medical conditions.</p>
10	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Organic Hemp Tea Bags</p> <p>CBDO.co.uk</p> <p>11 October 2018</p> <p>N/A</p> <p>The product satisfied the first limb of the definition. The product was presented for the treatment of a wide range or serious adverse medical conditions.</p>
11	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority's</p>	<p>Organic CBD E-Liquid For Vaping</p> <p>CBDO.co.uk</p> <p>11 October 2018</p> <p>N/A</p> <p>The product satisfied the first limb of the definition. The product was</p>

	Determination and reasons	presented for the treatment of a wide range or serious adverse medical conditions.
12	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Organic CBD Oil – 10ml</p> <p>CBDO.co.uk</p> <p>11 October 2018</p> <p>N/A</p> <p>The product satisfied the first limb of the definition. The product was presented for the treatment of a wide range or serious adverse medical conditions.</p>
13	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Organic Water Soluble CBD Drops – 10ml</p> <p>CBDO.co.uk</p> <p>11 October 2018</p> <p>N/A</p> <p>The product satisfied the first limb of the definition. The product was presented for the treatment of a wide range or serious adverse medical conditions.</p>
14	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Complete Joint Restore</p> <p>Bulk Powders</p> <p>20 February 2109</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product.</p> <p>The first limb was satisfied because the product was presented with claims and information relating to the treatment of inflammation and joint pain. The second limb was satisfied because the product was sold with a daily dosage level exceeding 1178mg/day of base glucosamine.</p>
15	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Date of notice:</p> <p>Panel Advice</p>	<p>Mobilise</p> <p>Bulk Powders</p> <p>20 February 2109</p> <p>N/A</p>

	Licensing Authority's Determination and reasons	<p>The product fell within both limbs of the definition of a medicinal product.</p> <p>The first limb was satisfied because the product was presented with claims and information relating to the treatment of inflammation and joint pain. The second limb was satisfied because the product was sold with a daily dosage level exceeding 1178mg/day of base glucosamine.</p>
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