NADVANCE LTD

REGULATORY STATUS STATEMENT

NAD+ BY NADVANCE

To Whom It May Concern

Business Description:

NADVANCE LTD is a United Kingdom-based company operating in the health and wellness sector, engaged in the development, distribution and sale of NAD+-related products intended to support general physiological function and wellbeing, in accordance with applicable food law and consumer protection requirements.

1. Introduction

This Regulatory Status Statement is issued on behalf of NADVANCE LTD ("the Company") for the purpose of setting out, in a clear and structured manner, the legal and regulatory position adopted in relation to the NADVANCE NAD+ product range within the United Kingdom.

This document is intended to:

- articulate the Company's classification position;
- demonstrate alignment with applicable UK food law; and
- provide a reasoned basis for distinguishing the relevant products from medicinal products and medical devices.

For the avoidance of doubt, this statement is a legal and regulatory position document. It does not constitute regulatory approval, certification, or authorisation by any competent authority.

2. Company Overview

NADVANCE LTD is a United Kingdom-based entity operating in the health and wellness sector. The Company's activities include the supply and distribution of NAD+-related products designed to support general physiological function and wellbeing.

The Company's commercial and regulatory position is that the relevant **NADVANCE** NAD+ products are to be presented, marketed and supplied as food supplements, subject to strict adherence to applicable legislation and regulatory guidance.

3. Product Scope

This statement applies to the **NADVANCE** NAD+ product range insofar as such products are:

- intended to supplement the normal diet or support physiological processes.

- not presented as having properties for treating, preventing or curing disease;
- not marketed as therapeutic, clinical or medicinal interventions; and
- supplied in compliance with applicable food law requirements.

Where any product, format, claim, or method of administration materially deviates from the above, a separate regulatory assessment may be required.

4. Applicable Legal and Regulatory Framework

The classification analysis is informed by the following legislation and guidance:

- **Food Supplements (England) Regulations 2003**
- **Food Safety Act 1990**
- **Assimilated Regulation (EU) No 1169/2011 (Food Information to Consumers)**
- **Assimilated Regulation (EC) No 1924/2006 (Nutrition and Health Claims)**
- **Directive 2002/46/EC (Food Supplements Directive)**
- **MHRA Guidance Note 8 – "A Guide to What is a Medicinal Product"**
- **Relevant principles under the Medical Devices Regulations 2002 (for distinction purposes)**

5. Regulatory Position

It is the considered position of **NADVANCE LTD** that, where the conditions set out in this statement are met, the **NADVANCE NAD+** product range is properly classifiable as a food supplement and does not fall within the definition of a medicinal product or medical devices.

This position is based on the presentation, intended purpose, and overall regulatory context of the product.

6. Basis for Food Supplement Classification

6.1 Nutritional and Physiological Role

NAD+ (nicotinamide adenine dinucleotide) is a naturally occurring coenzyme present in all living cells and is associated with cellular energy processes and physiological function.

Products relating to NAD+ may fall within the scope of food supplement regulation where they are:

- presented as supporting normal physiological functions;
- intended to supplement the diet or general wellbeing; and
- not positioned as therapeutic or disease-related interventions.

6.2 Absence of Medicinal Claims (Presentation Test)

Under UK law, a product is classified as medicinal by presentation if it is held out as treating or preventing disease.

NADVANCE products are not intended to be presented:

- as treatments for medical conditions;
- as therapeutic or clinical interventions;
- as preventing, curing or alleviating disease;
- as substitutes for medical advice or prescribed treatment.

All descriptions and communications are required to remain within the scope of general wellness and physiological support.

6.3 Function Test (Degree of Effect)

A product may be medicinal by function where it exerts a significant pharmacological, immunological or metabolic effect for therapeutic purposes.

The Company's position is that the relevant products:

- are not intended to exert a therapeutic or pharmacological effect of the type associated with medicines;
- are not administered with the primary purpose of restoring or correcting a pathological condition; and
- are instead positioned within the scope of general health support, consistent with food supplement use.

6.4 Method of Administration

While method of administration is a relevant factor, it is not determinative in isolation.

Classification must be assessed holistically, taking into account:

- intended purpose;
- product claims;
- consumer perception; and
- overall presentation.

NADVANCE recognises that certain delivery formats may attract regulatory scrutiny and therefore requires that:

- no medical or therapeutic framing is adopted;
- no clinical or treatment-based claims are made; and
- the product is not presented as a healthcare intervention.

7. Distinction from Medicinal Products

The **NADVANCE** product range is not a medicinal product on the basis that:

- it is not presented as treating or preventing disease;
- it is not marketed with therapeutic claims;
- it is not supplied as a licensed medicine;
- it is not positioned as a clinical treatment; and

- it does not require a marketing authorisation under medicines legislation.

8. Distinction from Medical Devices

The **NADVANCE** product range is not a medical device where:

- it is not intended for diagnosis, prevention, monitoring or treatment of disease;
- it is not presented as a therapeutic or clinical apparatus;
- it is not marketed as having a medical purpose; and
- any associated components are not independently positioned as regulated medical devices.

9. Conditions for Maintaining Food Supplement Status

The Company recognises that classification is dependent upon ongoing compliance. Accordingly, the following conditions are essential:

9.1 Labelling

- Clear identification as a food supplement (where applicable)
- Compliance with food labelling requirements
- No medicinal or disease-related claims

9.2 Advertising and Marketing

- No reference to treatment, cure, or prevention of disease
- No clinical or therapeutic claims
- Use of controlled, non-medicinal language

9.3 Product Safety and Quality

- Compliance with applicable food safety standards
- Appropriate quality control, traceability, and testing
- Maintenance of product specifications and safety documentation

9.4 Consistency Across Channels

All communications must be aligned, including:

- website content
- social media
- advertising campaigns
- influencer communications
- packaging and inserts

Any inconsistency may materially affect classification.

10. Claim Positioning (Summary Table)

Category	Food Supplement (Permitted)	Medicinal Product (Prohibited)
Purpose	Supports normal physiological function	Treats or prevents disease
Claims	Wellness / support / maintenance	Cure / treatment / therapy
Positioning	Supplement to diet	Medical intervention
Labelling	Food supplement	Medicine / therapeutic
Marketing	General wellbeing	Clinical outcomes

11. Conclusion

Subject to the conditions and assumptions set out in this document, it is the considered position of **NADVANCE LTD** that the **NADVANCE NAD+** product range is properly capable of classification as a food supplement under UK law, and does not constitute a medicinal product or medical device.

This conclusion is dependent upon:

- the absence of medicinal claims;
- lawful marketing and presentation;
- compliance with food legislation; and
- consistency across all public-facing materials.

12. Reservation and Disclaimer

This statement:

- is based on the information available at the date of issue;
- reflects the Company's regulatory position only;
- does not constitute regulatory approval or certification;
- may be updated in the event of changes to product, law, or regulatory interpretation.

13. Frequently Asked Questions (FAQ)

1. Is the Product a pharmaceutical or medicinal product?

No. The Product is not a pharmaceutical or medicinal product.

It is positioned and presented as a food supplement within the meaning of applicable UK food law. It is not intended to diagnose, treat, prevent or cure any disease, and no such claims are made in relation to the Product.

2. Does the Product require a prescription?

No. As a food supplement, the Product is not subject to prescription requirements.

However, consumers are encouraged to use the Product responsibly and, where appropriate, to seek independent professional advice before use.

3. What is the intended purpose of the Product?

The Product is intended to support general physiological function and wellbeing.

It is not intended to be used as a medical treatment, nor as a substitute for professional medical advice, diagnosis or therapy.

4. Does the Product make any medical or therapeutic claims?

No.

The Product is not presented as having properties for treating or preventing disease, nor as exerting a therapeutic or clinical effect. All descriptions of the Product are intended to remain within the scope of lawful food supplement and general wellness positioning.

5. Is **NAD+** safe?

NAD+ is a naturally occurring substance found in the human body and plays a role in normal cellular processes.

The safety of any specific product depends on its formulation, quality control, manufacturing standards and appropriate use. **NADVANCE LTD** implements appropriate quality and safety measures consistent with applicable food law requirements.

6. How is the Product regulated?

The Product is regulated under UK food law, including the **Food Supplements (England) Regulations 2003** and related legislation governing food safety, labelling and consumer information.

It is not subject to the regulatory framework applicable to medicinal products or medical devices, provided it is presented and used in accordance with its classification as a food supplement.

7. Does the method of delivery affect classification?

Classification is determined by a combination of factors, including intended purpose, presentation, claims and overall product context.

The method of delivery alone does not automatically determine whether a product is a medicinal product or food supplement; however, it is a relevant factor and must be considered alongside all other elements of the Product's presentation and use.

8. Can the Product replace medical treatment?

No.

The Product is not intended to replace medical treatment, diagnosis or advice. Consumers should consult a qualified healthcare professional in relation to any medical condition or treatment.

9. How does **NADVANCE** ensure compliance?

NADVANCE LTD adopts a structured compliance approach, including:

- alignment of product presentation with food law requirements
- controlled use of marketing language
- avoidance of medicinal or disease-related claims
- adherence to applicable safety, labelling and consumer protection standards
- ongoing review of regulatory developments

10. Is this document a regulatory approval?

No.

This document is a statement of regulatory position only. It does not constitute approval, certification or authorisation by any regulatory authority, including but not limited to the MHRA or any food standards body.

NADVANCE LTD

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