## ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES

## APPENDIX 5

# ACCEPTABILITY STUDIES FOR A NUTRITIONAL PRODUCT

**Note: These studies must conform with the principles of good clinical practice.**

**References:**
**EC Directive 2001 / 20 / EC**
**Guidance for Industry**

**E6 Good Clinical Practice: Consolidated Guidance**
**US Department of Health and Human Services: Food and Drug Administration**
**April 1996**

Patient acceptability is fundamental to the successful use of any product. It is important that all relevant aspects of acceptability are included in an application and that all flavours of a product are assessed for acceptability.

The objective of such studies will be to confirm that a product for which consideration has been requested has been found to be acceptable to patients for whom the product is intended, i.e. in accordance with the ACBS clinical indication(s).

**Thus studies undertaken in healthy volunteers will be of no value. Similarly sensory panels composed of healthy people will not meet this requirement.**

Acceptability studies will not, normally, be required for either gluten free or low protein foods.

In the case of infant feeds, the ACBS does not require palatability studies. Studies of gastrointestinal tolerance and compliance are required. Other aspects of acceptability such as changes in stool consistency may be required depending on the indication.

There is no requirement for these studies to be carried out in the NHS. What is important is the methodology used and the patient group rather than the physical location. However, cultural differences in acceptability should be considered.

All acceptability studies must be for at least 1 week and **at least 15 patients** must complete the study. A PRISMA/CONSORT type diagram should be included, which references the number of patients approached, the numbers recruited and what happened, particularly to those who did not complete the study.

## ASPECTS OF PATIENT ACCEPTABILITY INCLUDE:

## 1. GASTRO-INTESTINAL TOLERANCE

G-I tolerance studies must normally be carried out on at least 15 patients in the intended target group for a period of 1 week. Where nutritional products are intended for use in very rare conditions, such as inherited metabolic disorders, fewer patients are acceptable and advice should be sought from the ACBS Secretariat.

**1.1** Information must be provided about the timing, duration, cause and seriousness / severity of any adverse effects

**1.2** The following must be monitored and reported as a minimum:

**1.2.1** Diarrhoea and / or constipation

**1.2.2** Bloating and / or distension

**1.2.3** Nausea and / or vomiting

**1.2.4** Burping / flatulence / regurgitation

**1.2.5** Abdominal discomfort / pain

An easy to follow table must be included and, where appropriate, scales should be used. Quantitative data should be presented where appropriate. It is not the remit of the ACBS to interpret data.

## 2. PALATABILITY

**2.1** A formal procedure of assessment must be followed and the results of this must be available to the ACBS.

**2.2** Taste studies must normally be carried out on at least 15 patients in the intended target group (patients) for a period of 1 week

Where nutritional products are intended for use in very rare conditions, such as inherited metabolic disorders, fewer patients are acceptable and advice should be sought from the ACBS Secretariat.

Palatability applies primarily to products intended for oral consumption although there may be cases when they are helpful in assessing the acceptability of tube feed products.

Sensory evaluation panels normally comprise healthy individuals. However, this is not appropriate when developing products for specific patient groups. These **must** be carried out within the UK and also take due account of cultural differences. Such panels **must** comprise patients for whom the product is intended.

Taste panels **must** be composed of patients for whom the product being tested is intended. These **must** be carried out within the UK and also take due account of cultural differences.

General statements of support from healthcare professionals will not be considered.

## 3. COMPLIANCE

It is very important that data be provided about actual vs. prescribed intakes

Compliance studies must normally be carried out on at least 15 patients in the intended target group for a period of 1 week

Where nutritional products are intended for use in very rare conditions, such as inherited metabolic disorders, fewer patients are acceptable and advice should be sought from the ACBS Secretariat.

Examples of compliance could include:

**3.1** How many containers / portions / feeds / volume was the patient prescribed each day?

**3.2** How many containers / portions / feeds / volume were taken?

**3.3** What was the size / volume of each container / portion of feed?

**3.4** How was the product presented i.e. room temperature / heated / chilled / slushed / frozen?

**3.5** Was anything added to the product to make it more acceptable?

**3.6** Were any reasons for non-compliance identified?

**3.7** Viscosity data

This list is indicative but not exhaustive.