GUIDELINES ON THE APPROPRIATE USE AND PRESCRIBING OF INFANT FORMULA MILK IN PRIMARY CARE.

Colour key used in the guidelines

<table>
<thead>
<tr>
<th>Colour</th>
<th>Description</th>
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<tbody>
<tr>
<td>Green</td>
<td>Prescribe as first line</td>
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<tr>
<td>Yellow</td>
<td>Prescribe if treatment unsuccessful with first line</td>
</tr>
<tr>
<td>Red</td>
<td>Should only be prescribed for patients upon initiation or recommendation by a paediatrician or paediatric dietician. If started in primary care, patients must be immediately referred for further support.</td>
</tr>
</tbody>
</table>

Whilst these guidelines advise on appropriate prescribing of specialist infant formulae, breast milk remains the optimal milk for infants. This should be promoted and encouraged where it is clinically safe to do so and the mother is in agreement.

Requests to prescribe a formula before assessment by a GP, nurse, paediatric dietician or paediatrician must be for a first line product except where clinically justified.
INTRODUCTION
These guidelines aim to clarify which products and in which circumstances infant formulae can be prescribed for babies and young children in primary care. It also acts as a guide to prescribing quantities and prices. It advises on triggers for reviewing and discontinuing prescriptions and onward referral for dietetic and / or secondary care specialist advice.

Providing infant formulae inappropriately on prescription is considered inequitable prescribing as the prescription is supplied effectively at no charge but no equivalent support is available for breast feeding mothers or parents that purchase their own infant formulae from supermarkets or over the counter at pharmacies. Some patients may be eligible for supply of milk via the Healthy Start Scheme, for more information, refer to Healthy Start.

BACKGROUND
NICE Clinical Guideline 116 (February 2011) Food Allergy in children and young people covers the diagnosis and assessment of food allergy in children and young people in primary care and community settings. The care pathway from NICE which covers initial recognition to referral to specialist is available via Link to NICE guidelines on food allergy.

A limited range of products (food/milk substitutes) can be prescribed as drugs in line with advice from the Advisory Committee on Borderline Substances (ACBS) and these are defined in borderline substances. Any prescription written needs to be ‘ACBS’ approved. General Practitioners are reminded that the ACBS recommends products on the basis that they may be regarded as drugs for the management of specified conditions. Doctors should satisfy themselves that the products can safely be prescribed, that patients are adequately monitored and that, where necessary, expert hospital supervision is available. Link to BNFc borderline substances

QUANTITIES OF FORMULAE TO PRESCRIBE
The quantities below act as a guide for when any infant formula is prescribed. Infants may require more or less than this depending upon their age, size and the rest of their diet intake. It is advisable to prescribe only 1-2 tins initially for all formulas to assess tolerance and palatability. Recent correspondence from the paediatrician or paediatric dietician should be reviewed regularly.

<table>
<thead>
<tr>
<th>Age of child</th>
<th>Number of tins for 28 days</th>
<th>Approximate Daily equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 6 months old</td>
<td>10-13 x 400g tins or 6 x 900g tins</td>
<td>200g per day</td>
</tr>
<tr>
<td>6 – 12 months</td>
<td>7 – 13 x 400g tins or 3-6 x 900g tins</td>
<td>100-200g per day</td>
</tr>
<tr>
<td>Over 12 months</td>
<td>7 x 400g tins or 3 x 900g tins</td>
<td>100g per day</td>
</tr>
</tbody>
</table>

For powdered formula:
Prescribe an equivalent volume of formula to the child’s usual intake until an assessment has been performed and recommendations made by a paediatrician or paediatric dietician.

Powdered formulae to be used routinely except for high risk infants (pre-term, low birth weight and immunocompromised) and liquid high energy formulae specified in the guidelines.
For high risk infants, using ready to feed liquid formula, which is sterile, in place of making up powdered formula is considered the safest option. Guidance for health professionals on safe preparation, storage and handling of powdered infant formula is available via http://www.food.gov.uk/multimedia/pdfs/formulaguidance.pdf

A guide to bottle feeding is available via Start4life Guide to bottle feeding
## Prescribing, Reviewing and Stopping Formulae

### Secondary Lactose Intolerance

NOTE: Primary lactose intolerance is less common than secondary intolerance and does not usually present until later childhood or adulthood.

<table>
<thead>
<tr>
<th>Condition/Indication</th>
<th>Diagnosis</th>
<th>Treatment/Review Criteria</th>
<th>Name of Formula and FP10 price (as at July 2013)</th>
<th>Criteria for stopping Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary Lactose Intolerance</td>
<td>Usually occurs following an infectious gastrointestinal illness. Symptoms include: abdominal bloating, wind, increased (explosive) and loose, green stools. Lactose Intolerance should be suspected in infants who have had symptoms that persist for more than 2 weeks. Diagnosis is the resolution of symptoms, usually within 48 hours, once lactose is removed from the diet.</td>
<td>Treatment with lactose free formula for 2-8 weeks to allow symptoms to resolve, then reintroduction to standard formula/milk products slowly into the diet. If symptoms do not resolve on commencing standard infant formula then refer to a Dietician. For treating lactose intolerance in infants who have been weaned these formula should be used in conjunction with a milk free diet. If an infant presents with suspected Lactose intolerance at one year or older and is on cow’s milk, then a lactose free full fat cow’s milk can be used for the treatment period. This is available in supermarkets. Note: the use of Lactase drops is not common practice</td>
<td>SMA LF* (430g tub - £4.60)</td>
<td>Can be used for a maximum of 8 weeks without review. Age restriction: birth to 2 years old. Lactose free infant formulas can be bought at a similar cost to standard infant formula and prescribers should consider the need to prescribe. The Clinical Commissioning Group supports the position that an initial prescription is appropriate to allow parents time to source further supplies from the retailer of their choice. Most pharmacies and many supermarkets can obtain stock in a few days.</td>
</tr>
</tbody>
</table>

### Cow’s Milk Protein Allergy (CMPA)

(continued)

<table>
<thead>
<tr>
<th>Condition/Indication</th>
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<th>Criteria for stopping Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cow’s Milk Protein Allergy (CMPA)</td>
<td>Suspect CMPA after careful history taking. Refer to NICE guidelines (Food Allergy in Children and Young People, Feb 2011) - NICE CG116 for history taking and symptoms. Symptoms can include frequent</td>
<td>Trial of extensively hydrolysed formula for 2 weeks for tolerance. It may take up to 4-6 weeks for symptoms to resolve. These infants should be reviewed by/referred to a paediatric dietician. Refer to NICE guidelines for when to refer to secondary care.</td>
<td>Nutramigen lipil 1* For under 6 months (400g tub - £9.29) Nutramigen lipil 2 For over 6 months (400g tub - £8.95) Similac* (400g tub - £9.10)</td>
<td>Continue formula until infant has grown out of allergy or they are 2 years old. At 6 months change prescription to Nutramigen 2 unless a dietician has advised otherwise. The same</td>
</tr>
</tbody>
</table>
**Condition/Indication** | **Diagnosis** | **Treatment/Review Criteria** | **Name of Formula and FP10 price (as at July 2013)** | **Criteria for stopping Formula**
---|---|---|---|---
Cow’s Milk Protein Allergy (CMPA) | regurgitation, gastro-oesophageal reflux, vomiting, diarrhoea, and constipation with or without perianal rash, blood in stools, eczema, distress, colic. Most babies presenting with colic, restlessness and/or crying do not have a CMP allergy. A health visitor’s advice should be sought to ensure problems with feeding technique and formula reconstitution are addressed. | **NOTE:** Lactose free formulas are not suitable for treating CMPA. The taste of hydrolysed formulae is unpleasant and it has a bitter smell therefore compliance can be improved by using a bottle, closed cup or a straw. Younger infants take hydrolysed formulas more readily than older infants. Infants who do not tolerate one formula may tolerate another. Therefore it is worth prescribing only 1 or 2 tins initially. If not tolerated or taken after perseverance, trying another comparable formula. Amino acid based formulae are indicated when hydrolysed formulas do not resolve symptoms or when there is evidence of severe or multiple allergies. Where a specialist formula is prescribed, this should be with a care plan and a review date with the paediatric dietician to which the repeat interval of the prescription is aligned. | **Aptamil Pepti 1**<sup>1</sup> For under 6 months Use if infant not tolerating or taking Nutramigen. Contains some lactose. (400g tub - £8.62) 900g tub - £19.39) | These children should be reviewed every 6 months as paediatric allergy will often resolve. Refer to NICE guidelines CG 116 for which children should be challenged with cow’s milk in secondary care setting. Children over 2 years old with multiple allergies and poor diet, refer to specialist. Nutramigen AA and Neocate LCP: To establish if children taking these products have grown out of the allergy will require secondary / tertiary care input. **Neocate Active** and **Neocate Advanced** are highly specialised products, therefore should only be used by secondary or tertiary care and not prescribed in infants under age of one year. Do not advise sheep or goats milk. |
| (continued) | (continued) | Soya Formula can be considered in infants over 6 months old for CMPA. It may also be used in infants over 6 months who have grown out of the CMPA. It is also useful in infants with CMPA and eosinophilic oesophagitis. | **Soya Formula**<sup>2</sup> | |

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<sup>1</sup>Appplies for Aptamil Pepti 1 and 2.

<sup>2</sup>These children should be reviewed every 6 months as paediatric allergy will often resolve.

<sup>3</sup>Refer to NICE guidelines CG 116 for which children should be challenged with cow’s milk in secondary care setting.

<sup>4</sup>Children over 2 years old with multiple allergies and poor diet, refer to specialist.

<sup>5</sup>Nutramigen AA and Neocate LCP: To establish if children taking these products have grown out of the allergy will require secondary / tertiary care input.

<sup>6</sup>**Neocate Active** and **Neocate Advanced** are highly specialised products, therefore should only be used by secondary or tertiary care and not prescribed in infants under age of one year.

<sup>7</sup>Do not advise sheep or goats milk.
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</thead>
<tbody>
<tr>
<td>Allergy (CMPA)</td>
<td></td>
<td>months. The chief medical officer advises that soya formula should not be used as the first line treatment for CMPA for children under 6 months. Soya Formula should be considered in infants who will not take a first or second line formula on this list (over 6 months).</td>
<td>Wysoy®&lt;sup&gt;1&lt;/sup&gt; (430g tub - £4.59) 860g tub - £8.75)</td>
<td>due to cross reactivity. Refer to NICE guidelines (2011)&lt;sup&gt;1&lt;/sup&gt; for which children should be challenged with cow’s milk in secondary care setting. Soya formulas can be bought at a similar cost to standard infant formula and prescribers should consider the need to prescribe. The Clinical Commissioning Group supports the position that an initial prescription is appropriate to allow parents time to source further supplies from the retailer of their choice. Most pharmacies and many supermarkets can obtain stock in a few days. Beyond 2 years calcium enriched soya milk can be used as an alternative source of milk. This can bought at supermarkets.</td>
</tr>
</tbody>
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Date approved: 14<sup>th</sup> August 2013
Review date: August 2015
## Gastro-oesophageal Reflux (GOR)

A diagnosis of GOR is made clinically from a history of effortless vomiting occurring after meals. Rule out overfeeding by establishing volume of feed as initial treatment.

### Symptoms of GOR may include:
- Regurgitation of a significant volume of feed
- Reluctance to feed
- Distress / crying at feed times
- Small volumes of feed being taken

Infants with faltering growth should be referred to paediatric services. For other infants the following can be tried:

**STEP ONE:**
50% of babies have some degree of reflux. If baby is vomiting persistently (not projectile) but the baby is thriving and not distressed, reassure parents and monitor.

Provide advice on feeding positioning, avoidance of over feeding and activity following a feed.

**STEP TWO:**
If the bottle fed infant is not settled and not gaining weight – trial with thickening formula or thickening agent such as infant Gaviscon. These formulae should not be used in conjunction with antacid medication or thickeners.

Review after one month. If no improvement in symptoms, may need further investigation by a Paediatrician. These infants require regular review.

Breastfed babies with GOR may continue to be breastfed; further guidance on supporting a breastfed baby with GOR is available via a health visitor.

### Name of Formula and FP10 price (as at July 2013)

<table>
<thead>
<tr>
<th>Formula</th>
<th>Price</th>
<th>Criteria for stopping Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enfamil AR®</strong></td>
<td>£3.12</td>
<td>Once vomiting resolves return to standard formula.</td>
</tr>
<tr>
<td><strong>Aptamil Anti-Reflux®</strong></td>
<td>£10.99</td>
<td>Not to be used for a period of more than 6 months after which a normal formula can be used.</td>
</tr>
<tr>
<td><strong>SMA Staydown®</strong></td>
<td>£6.62</td>
<td>Reflux often resolves at 6 months of age or start of weaning.</td>
</tr>
</tbody>
</table>

**NOTE:** alert parents to different procedure for making up feed on tin (required fridge cooled pre-boiled water) which may place the milk at increased risk of contamination.

*The Clinical Commissioning Group supports the position that an initial prescription is appropriate to allow parents time to source further supplies from the retailer of their choice. Most pharmacies and many supermarkets can obtain stock in a few days.*
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<tr>
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<th>Criteria for stopping Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-term Infants</td>
<td>These children will have had their formula commenced in hospital. It is started for babies born before 34 weeks gestation. &lt;br&gt; <strong>NOTE:</strong> This formula should not be used in primary care to promote weight gain in term infants.</td>
<td>Any infant discharged on these formula should have their growth (this includes weight, length and head circumference) monitored by the health visitor.</td>
<td><strong>Nutriprem 2</strong>&lt;sup&gt;®&lt;/sup&gt; &lt;br&gt; (900g tub - £10.28) &lt;br&gt; (200ml carton - £1.54)</td>
<td>Up to 6 months corrected age (i.e. six months plus the number of weeks premature added on).&lt;br&gt; These formulas should be stopped if there is excessive weight gain. If there are concerns regarding growth, refer to the paediatric dietician. Standard formula or follow on formula would be the appropriate step.</td>
</tr>
<tr>
<td>Faltering growth</td>
<td>Faltering growth is indicated when the weight of an infant falls below the bottom centile (0.4th) or crosses 2 centiles downwards on a growth chart. &lt;br&gt; The height, as well as weight, of a child needs to be measured in order to properly interpret changes in the latter. It is not possible to detect growth faltering without using appropriate growth charts.</td>
<td>It is important to consider the reason for faltering growth e.g. iron deficiency anaemia, constipation, GOR or a child protection issue and treat accordingly.&lt;br&gt; Before commencing a high energy formula ensure parents/carers are offered food first advice on suitable high calorie foods if the infant is weaned.&lt;br&gt; Refer any infant being commenced on a high calorie formula to a Dietitian.</td>
<td><strong>SMA Gold Prem 2</strong>&lt;sup&gt;®&lt;/sup&gt; &lt;br&gt; (400g tub - £4.57)</td>
<td>These formulas should be used until 18 months or 8kgs. After this time, if the child is growing well, the prescription should be discontinued. If on-going concerns about weight gain refer for a dietetic assessment. Should be under the care of a paediatrician to investigate cause of faltering growth.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>SMA High Energy</strong>&lt;sup&gt;®&lt;/sup&gt; &lt;br&gt; (250ml carton - £2.08)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Similac High Energy</strong>&lt;sup&gt;®&lt;/sup&gt; &lt;br&gt; 120ml bottle (£1.23) 200ml bottle (£2.06)</td>
<td></td>
</tr>
<tr>
<td>Condition/Indication</td>
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<tr>
<td>----------------------</td>
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<td>-----------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>Faltering Growth</td>
<td>(continued)</td>
<td>(continued) If is important to rule out possible disease-related/medical causes for the faltering growth.</td>
<td>Note: All infants on a high energy formula will need growth (weight and length/height) monitoring to ensure catch up growth and appropriate discontinuation of formula to minimise excessive weight gain</td>
<td>Infatrini ® (100ml bottle - £1.03) (200ml bottle - £1.94)</td>
</tr>
</tbody>
</table>

Other points to consider:
- Infants with CMPA may need calcium supplementation.
- All infants on a specialised formula should be reviewed regularly by the dietician and / or doctor in line with NICE guidelines – CG116, and if appointments are missed, repeat prescriptions should not be given.
- From 2 years of age, children with CMPA, who are eating a varied diet, can switch from a hypoallergenic formula to ready-made milks, e.g. fortified soya (if appropriate), pea, or oat milk.
- Rice milk is not recommended until at least 4 ½ years of age because of the high levels of arsenic contamination found in this milk. [http://food.gov.uk/multimedia/pdfs/fsis0209arsenicinrice.pdf](http://food.gov.uk/multimedia/pdfs/fsis0209arsenicinrice.pdf)
- Review repeat prescription quantity at 3 month intervals and adjust according to current requirements.

**USEFUL CONTACTS**

**Paediatric Nutrition and Dietetic Service:** Paediatric dieticians can be contacted via telephone number 01634 830000 extension 5908

Referral process: Letter requesting diagnosis addressed to Paediatric Dieticians, Department of Nutrition and Dietetics, Medway Community Healthcare, COAST office, Green Zone, Level 2, Medway Maritime Hospital, Windmill Road, Gillingham, Kent ME7 5NY.

Health Visiting Service: Medway Community Healthcare, 01634 382882

**References:**
1. British National Formulary (BNF) for Children 2013-14

This document has been adapted from NHS Midlands and East PrescQIPP ‘Prescribing Specialist Infant Formula in Primary Care’.

**Appendix 1: Recommendations for Management of Faltering Growth, Gastro-oesophageal reflux and Suspected Lactose Intolerance**
**CLINICAL ASSESSMENT**

### Faltering Growth
i.e. weight of an infant falls below the bottom centile (0.4<sup>th</sup>) or crosses 2 centiles downwards on a growth chart.

Health Visitor to check feeding techniques /adequate volumes being taken. If weaned then to advise high calorie weaning.

If no improvement refer to Paediatrician and / or paediatric dietician.

High calorie formula may be indicated.
- **SMA High Energy<sup>®</sup> 250ml carton**
- **Similac High Energy<sup>®</sup>**
- **Infantrin<sup>®</sup> 100ml / 200ml bottle**

### Gastro-oesophageal Reflux (GOR)
A diagnosis of GOR is made clinically from a history of effortless vomiting occurring after meals. Rule out overfeeding by establishing volume of feed as initial treatment.

Provide advice on feeding positioning, avoidance of over feeding and activity following a feed.

If no improvement to try pre-thickened formulas.
- **Enfamil AR<sup>®</sup> 400g tub**
- **Aptamil Anti-Reflux<sup>®</sup> 900g tub**
- **SMA Staydown<sup>®</sup> 900g tub**

Pre-thickened formulas can be bought at a similar cost to standard infant formula; prescribers should consider the need to prescribe. First prescription can be provided to allow parents time to source further supplies.

### Suspected Lactose Intolerance
If symptoms include diarrhoea, wind, colic, perianal irritation and redness.

Try lactose free formula
- **SMA LF<sup>®</sup> 430g tub**
- **Enfamil O-Lac<sup>®</sup> 400g tub**

Treatment with lactose free formula for **2-8 weeks** to allow symptoms to resolve, then reintroduction to standard formula/milk products slowly into the diet.

Lactose free infant formulas can be bought at a similar cost to standard infant formula; prescribers should consider the need to prescribe. First prescription can be provided to allow parents time to source further supplies.

### If still no improvement
Consider CMP intolerance/allergy (see Appendix 2) and further investigation by paediatrician.

### If no improvement
Then consider CMP intolerance/allergy (see Appendix 2)

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**Appendix 2 - Recommendations for Management of Cow’s Milk Protein (CMP) suspected allergy**

<table>
<thead>
<tr>
<th>Age of child</th>
<th>Approximate Number of tins / 28 days</th>
</tr>
</thead>
<tbody>
<tr>
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Only healthcare professionals with appropriate competencies should take clinical history to assess for suspected food allergy.

Initial recognition. Consider food allergy in a child or young person who:

- Has one or more of the signs and symptoms in Box 1 (pay particular attention to persistent symptoms that involve different organ systems) or
- Has had treatment for atopic eczema, gastro-oesophageal reflux disease or chronic gastrointestinal symptoms (including chronic constipation) but their symptoms have not responded adequately

**CLINICAL ASSESSMENT**

Cow’s Milk Protein Intolerance/Allergy (CMPI/A)

Mild to moderate CMP allergy symptoms
If breastfeeding - mum to start milk free diet

Mild to moderate CMP allergy symptoms
If formula fed – try extensively hydrolysed formula (eHF)

Severe alarm allergy symptoms
If formula fed - try Amino Acid Formula (AAF)

Symptoms should resolve within 2-6 weeks

If breastfeeding - mum to start milk free diet

If formula fed - try extensively hydrolysed formula (eHF)

If no improvement, consider AAF and refer to paediatric dietician
OR
Refer to NICE guidelines CG 116 for which children should be challenged with cow’s milk in secondary care setting.

For recommended quantities to prescribe, see Appendix 1.

**Box 1. Signs & Symptoms of possible food allergy**¹

**IgE Mediated (Type I)**

The skin
- Pruritus
- Erythema
- Acute Urticaria (localised or generalised)
- Acute angioedema (most commonly in the lips, face and around the eyes)

Gastro-Intestinal System
- Angioedema of the lips, tongue & palate
- Oral pruritus
- Colicky abdominal pain
- Vomiting
- Diarrhoea

Respiratory System²
- Upper respiratory tract symptoms – nasal itching, sneezing, rhinorrhea or congestion (with or without conjunctivitis)
- Lower respiratory tract symptoms (cough, chest tightness, wheezing or shortness of breath)

Other
- Signs or symptoms of anaphylaxis or other systemic allergic reactions

**Non-IgE Mediated (Type IV)**

The skin
- Pruritus
- Erythema
- Atopic eczema

Gastro-intestinal System
- Gastro-oesophageal reflux disease
- Loos or frequent stools
- Blood and/or mucus in stools
- Abdominal pain
- Infantile colic
- Food refusal or aversion
- Constipation
- Perianal redness
- Pallor and tiredness
- Faltering growth plus one or more gastrointestinal symptoms above (with or without significant atopic eczema)

Respiratory System³
- Lower respiratory tract symptoms (cough, chest tightness, wheezing or shortness of breath)

¹ Note: this list is not exhaustive – the absence of these symptoms does not exclude food allergy

² Usually in combination with one or more of the above

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Review date: August 2015

For recommended quantities to prescribe, see Appendix 1.
Appendix 3: Template letters from the paediatric dietetic service.

PRESCRIPTION REQUEST for DIETETIC PRODUCTS

COAST Office
Medway Maritime Hospital
Windmill Road
Gillingham
Kent
01634 830000 extn 5908

Dear Dr_______  
Re:                                 DOB               NHS No.
Address:

A prescription for the above patient is necessary because of:

- Weight loss / poor weight gain / excessive weight gain;
- Allergy / intolerance;
- Intolerance of current feed / feed volume;
- Alteration in medical condition;
- Dislike of currently prescribed product;
- Not meeting requirements for certain nutrients;
- Other _____________________________

Please prescribe the following product(s) for a period of _____ months:

Please can you inform the patient or parents/carers when the prescription is ready.

I shall review ______ in clinic in ______ months and let you know if a prescription is still required.

Thank you for your help. Please contact us if you have any queries or concerns.

Yours sincerely

xxxxxxxxx
Specialist paediatric dietician

---

COAST Office
Medway Maritime Hospital
Windmill Road
Gillingham
Kent
01634 830000 extn 5908

Dear Dr_______

Re:                                 DOB               NHS No.
Address:

The parents/carers of the above child have failed to contact us to book a follow-up appointment and therefore he / she has been discharged from our service.

_______ is currently being prescribed supplements / specialised dietary products and one of the purposes of the follow-up appointment was to review the current requirement for these items as this can change over time and with age. This has not been possible, however, therefore you may wish to consider whether it is appropriate to continue to issue repeat prescriptions.

We would be pleased to see this child in clinic again if you wish to re-refer.

Yours sincerely

xxxxxxxxx
Specialist paediatric dietician

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