

## Attachment 1

Criteria for Labeling Permission for "Foods for Special Dietary Uses" (hereinafter referred to as "FOSDU")

### Section I Range of foods subject to labeling permission for FOSDU

1. Foods subject to labeling permission for "FOSDU" under Article 26, paragraph (1) of the Health Promotion Act (Act No. 103 of 2002) are foods for medical uses, powdered formulas for pregnant or lactating women, infant formulas (referring to infant formulas in powdered form and infant formulas in liquid form), and foods for people with dysphagia (including thickeners).

2. Among foods for medical uses, foods in the following food groups (hereinafter referred to as "Foods for medical uses (Approval Criteria form)") are subject to labeling permission for FOSDU granted according to the permission criteria prescribed in Section II, 3, and other foods (hereinafter referred to as "Foods for medical uses (Individual Evaluation form)") are subject to labeling permission for FOSDU granted through individual evaluation in accordance with the provisions of Section II, 4.

- (1) Low-protein food products
- (2) Allergen-free food products
- (3) Lactose-free food products
- (4) Comprehensive nutrition food products

3. With regard to foods for medical uses, a label indicating suitability for a special use should correspond to any one of the following items. Care should be taken to ensure that foods carrying these types of labels are not put on sale without permission.

- (1) Labels simply stating that the food is suitable for patients; for example, statements meaning "for patients," "diet for patients," etc.
- (2) Labels stating that the food is suitable for a specific disease; for example, statements meaning "for patients with diabetes," "for patients with kidney diseases," "suitable for hypertensive patients," etc.

However, this type is not limited only to phrases indicating the name of a specific disease, but it also includes phrases which are considered to have the same effect on consumers as indicating the name of a specific disease; for example, phrases meaning "Does not affect blood sugar level," "Suitable for patients with edema," etc.

- (3) Labels indicating a name similar to that of a food in a food group eligible for permission, which may give an impression that the food is for patients; for example, names meaning "low-protein food products," "hypoallergenic food," etc.

However, in the case of foods with a claim of low protein content, this does not apply to products with a claim meaning "low protein content (x% of the general value of [name of the food])" or "low protein content, x% lower than that of the general value of [name of the food]," so long as they are

labeled with the nutrient declaration and accompanied by a statement meaning that "This product is not FOSDU (foods for patients) permitted by the Consumer Affairs Agency," because products labeled in this manner would not be mistaken by patients as foods for special dietary uses.

4. Among infant formulas, foods in the following food groups are subject to labeling permission for FOSDU granted according to the permission criteria prescribed in Section IV.

(1) Infant formulas in powdered form

(2) Infant formulas in liquid form

5. Among foods for people with dysphagia (including thickeners), foods in the following food groups are subject to labeling permission for FOSDU granted according to the permission criteria prescribed in Section V.

(1) Foods for people with dysphagia

(2) Thickeners

## Section II Criteria for Labeling Permission for "Foods for patients"

### 1. Basic criteria

(1) The food has an adjusted nutritional composition or is specially processed, and it is recognized from a medical and nutritional point of view as being suitable for patients who require special nutritional consideration.

(2) The claim of the special uses of the food is appropriate for foods for patients.

(3) The composition or characteristics of the food can be confirmed by appropriate test methods.

### 2. General criteria

(1) The food is effective when used in compliance with the instructions for use and is easy to use.

(2) The quality of the food is not inferior to ordinary food.

(3) The targeted consumers of the food cover a considerably wide range of people or the food meets a particular need of patients.

(4) Without using the food, it is difficult to conduct or continue diet therapy.

The term "diet therapy" used herein refers to having a patient consume a nutritionally controlled diet based on medical and nutritional knowledge following a physician's instructions in order to cure a disease or prevent the recurrence or progression of a disease.

### 3. Foods for medical uses (Approval Criteria form)

(1) In addition to the basic criteria and general criteria defined in Section II, 1 and 2, Foods for medical uses (Approval Criteria form) should conform to the "Permission Criteria by Food Group" in Annex 1 (standards, range of acceptable claims of special dietary uses, and Labeling requirements). With regard to powdered and liquid milk for infants among foods for medical uses (especially allergen-free food products and lactose-free food products), the content of nutritional composition other than those acceptable under the permission criteria for foods for medical uses (excluding nutritional composition specially used for nutritional therapy) should conform to the criteria for the nutritional composition of infant formulas listed in Table 2.

Note that Labeling requirements includes the items of information set forth in Article 8, paragraph (1) of the Cabinet Office Order on Labeling Permission for Special Dietary Uses under the Health Promotion Act (Cabinet Office Order No. 57 of 2009; hereinafter referred to as the "Cabinet Office Order") and also includes other items of particular importance.

(2) With regard to the application of the Permission Criteria by Food Group in the case of a food that has no equivalent in kind in any food group, the provisions in the Standards section concerning the comparison with the content of specific composition of ordinary foods of similar kinds do not apply. The decision to grant permission or not should be made for each food in an application for permission by individually evaluating whether its composition and intended use are suitable to be permitted as foods for medical uses. In this case, the food should be able to be used as an alternative to the conventional food consumed by patients in terms of the characteristics, purpose of use, and form of consumption. With regard to low-protein food products, allergen-free food products, and lactose-free food products, the groups of foods originally not containing the composition listed in 1 in the respective Standards sections are not eligible as the subject of an application for permission.

#### 4. Foods for medical uses (Individual Evaluation form)

(1) In addition to the basic criteria and general criteria defined in Section II, 1 and 2, it is appropriate to conduct scientific evaluation individually with regard to some types of foods by a method similar to the evaluation method applicable to foods for specified health uses, as provided in Attachment 1 "Guidelines for Handling and Guidance on Evaluation of Foods for Specified Health Uses" of "Notification regarding Labeling Permission for Foods for Specified Health Uses" (Shou-Shoku-Hyou No. 259 of October 30, 2014), in order to provide appropriate information to patients with specific diseases. From this viewpoint, such foods are permitted to be labeled as foods for medical uses based on individual evaluation.

(2) Individual evaluation to grant labeling permission for foods for medical uses is conducted to verify whether the food in question meets all the requirements defined in (A) to (K) below.

The term "participating nutrients" used herein refers to food composition that participate in curing a disease when diet therapy is conducted.

(A) The food is expected to demonstrate an effect that helps achieve the purpose of the diet therapy for curing a specific disease.

(B) There is medical and nutritional evidence to show that the food or its participating nutrients are effective in diet therapy for patients.

(C) It is medically and nutritionally possible to establish an appropriate method of using the food or its participating nutrients in diet therapy for patients.

(D) The food or its participating nutrients are safe as judged from the past consumption generally (they must be safe in terms of food sanitation and must also have a history of human consumption, and must not cause health problems or unbalanced nutrition by excessive intake, in light of the amount and method of intake).

(E) The following are clearly defined for participating nutrients.

(a) Physical, chemical, and biological properties, and the test methods thereof

(b) Qualitative and quantitative test methods

(F) The form of consumption of the food does not significantly differ from that of similar kinds of food (foods for medical uses are supposed to be consumed continuously in their daily meals as part of diet therapy and are required to replace what patients have previously consumed, without changing their eating styles significantly, so as to facilitate diet therapy.)

(G) The food is consumed on a daily basis, rather than just on rare occasions.

(H) In principle, the food has a normal form, rather than shaped as tablets or capsules.

(I) The food or its participating nutrients are not included in Attachment 2 "List of Ingredients (Raw Materials) Used Exclusively for Pharmaceuticals" of Annex "Criteria Concerning Range of Pharmaceuticals" of "Notification regarding Guidance and Regulation for Unapproved/Unauthorized Pharmaceuticals" (Yaku-Hatsu No. 476 of June 1, 1971).

(J) The manufacturing method and product control method are clearly described.

(K) In the case of powdered and liquid milk for infants, the content of nutritional composition (excluding nutritional composition specially used for nutritional therapy) conforms to the criteria for the nutritional composition of infant formulas listed in Table 2.

(3) To decide whether or not to grant permission for foods for medical uses (Individual Evaluation form), the Consumer Affairs Agency organizes a screening system consisting of experts with medical and nutritional knowledge and makes a decision based on their opinions.

(4) If permission is granted for a food for medical uses (Individual Evaluation form), the label must contain the following information.

(A) A statement that the food is for patients

(B) A statement that the food should be taken only when directed by a physician

(C) A statement that the food is suitable for XX disease.

(D) A statement that it is appropriate to use the food upon receiving advice from a physician and registered dietitian and following their instructions

(E) A statement that the food is suitable as a part of diet therapy, and that high intake of the food does not lead to curing the disease

(F) Items required to be displayed as conditions for labeling permission, if there are any such items

(G) If the food is known for causing a disorder due to overconsumption or if there is a risk of such disorder, this must be stated based on the references attached to the application form.

### Section III Criteria for Labeling Permission for "Powdered Formulas for Pregnant or Lactating Women"

#### 1. Range of application of labeling for powdered formulas for pregnant and lactating women

The range of labeling for a powdered formula for pregnant and lactating women subject to permission applies to labels stating that the powdered formula is suitable for pregnant and lactating women, using medical and nutritional expressions.

#### 2. Criteria for labeling permission for powdered formulas for pregnant and lactating women

Labeling permission for a powdered formula for pregnant and lactating women is granted to a food

that conforms to the criteria for the nutritional composition as listed in Table 1.

Table 1

Composition	Content in a daily intake amount of product
Energy	314 kcal or less
Protein	10.44 g or more
Total fat	2.30 g or more
Sugar	23.66 g or more
Niacin <sup>*1</sup>	0.29 mg or more
Vitamin A <sup>*2</sup>	456 µg or more
Vitamin B <sub>1</sub>	0.86 mg or more
Vitamin B <sub>2</sub>	0.76 mg or more
Vitamin D	7.5 µg or more
Calcium	650 mg or more

\*1 Total amount of nicotinic acid and nicotinamide plus 1/60 of tryptophan

\*2 Total amount of retinol, α-carotene, and β-carotene and others showing the effect of Vitamin A

### 3. Labeling requirements

If permission is granted for a powdered formula for pregnant and lactating women, the label must contain the following information.

- (1) Wording meaning "Powdered formula for pregnant and lactating women"
- (2) The amount of nutritional composition
- (3) Standard usage

## Section IV Criteria for Labeling Permission for "Infant Formulas"

### 1. Range of application of labeling for infant formulas

The range of labeling for infant formulas requiring permission applies to labels stating that the food is suitable as an alternative to breast milk, using medical and nutritional expressions.

### 2. Criteria for labeling permission for infant formulas

Labeling permission for infant formulas is granted to a food that conforms to the following criteria.

- (1) The food is approved as "powdered infant formula" or "liquid infant formula" under the Order on Compositional Standards for Milk and Milk Products (Order of Ministry of Health and Welfare No. 52 of 1951; hereinafter referred to as the "Ministerial Order on Milk").
- (2) The food conforms to the criteria for the nutritional composition of infant formulas listed in Table 2.

Table 2

	Energy at standard concentration (per 100 ml)
Energy	60–70 kcal

Composition	Composition per 100 kcal
Protein (Nitrogen conversion factor: 6.25)	1.8–3.0 g
Total Fat	4.4–6.0 g
Carbohydrates	9.0–14.0 g
Niacin <sup>*1</sup>	300–1500 µg
Pantothenic acid	400–2000 µg
Biotin	1.5–10 µg
Vitamin A <sup>*2</sup>	60–180 µg
Vitamin B <sub>1</sub>	60–300 µg
Vitamin B <sub>2</sub>	80–500 µg
Vitamin B <sub>6</sub>	35–175 µg
Vitamin B <sub>12</sub>	0.1–1.5 µg
Vitamin C	10–70 mg
Vitamin D	1.0–2.5 µg
Vitamin E	0.5–5.0 mg
Folic acid	10–50 µg
Inositol	4–40 mg
Zinc	0.5–1.5 mg
Chlorine	50–160 mg
Potassium	60–180 mg
Calcium	50–140 mg
Iron	0.45 mg or more
Copper	35–120 µg
Selenium	1–5.5 µg
Sodium	20–60 mg
Magnesium	5–15 mg
Phosphorus	25–100 mg
α- Linolenic acid	0.05g or more
Linoleic acid	0.3–1.4 g
Calcium / Phosphorus	1–2
Linoleic acid / α- Linolenic acid	5–15

\*1 Total amount of nicotinic acid and nicotinamide

\*2 Amount of retinol

### 3. Labeling requirements

#### (1) Infant formulas in powdered form

If permission is granted for a powdered infant formula, the label must contain the following information.

(A) Wording meaning "powdered infant formula"

(B) A statement that the food can be used as an alternative to breast milk (this should be accompanied by a note that breast milk is the best for infants)

(C) A statement that it is appropriate to use the food upon receiving advice from a physician and registered dietitian and following their instructions

(D) Standard formula preparation

(E) A statement that the food should be used in consideration of differences between individual infants

#### (2) Infant formulas in liquid form

If permission is granted for a liquid infant formula, the label must contain the following information.

(A) Wording meaning "liquid infant formula"

(B) A statement that the food can be used as an alternative to breast milk (this should be accompanied by a note that breast milk is the best for infants)

(C) A statement that it is appropriate to use the food upon receiving advice from a physician and registered dietitian and following their instructions

(D) Standard formula preparation

(E) A statement that the food should be used in consideration of differences between individual infants

## Section V Criteria for Labeling Permission for "Foods for People with dysphagia (including thickeners)"

### 1. Range of application of labeling for foods for people with dysphagia (including thickeners)

#### (1) Foods for people with dysphagia

The range of labeling for foods for people with dysphagia (foods intended to facilitate swallowing and to prevent accidental aspiration and suffocation) subject to permission applies to labels stating that the food is suitable for people with dysphagia, using medical and nutritional expressions.

#### (2) Thickeners

The range of labeling for thickeners (foods used to thicken liquid in order to facilitate swallowing and to prevent accidental aspiration and suffocation) subject to permission applies to labels stating that the food is suitable for people with dysphagia, focusing on their thickening effect, using medical and nutritional expressions.

### 2. Criteria for labeling permission for foods for people with dysphagia (including thickeners)

(1) Foods for people with dysphagia

Labeling permission for foods for people with dysphagia is granted to a food that conforms to the following criteria.

(A) Basic criteria

- (a) The food is suitable from a medical and nutritional point of view for consumption by people with dysphagia.
- (b) The food has actually been taken by people with dysphagia.
- (c) The claim of the special uses of the food is appropriate for foods for people with dysphagia.
- (d) The food is easy to use.
- (e) The quality of the food is not inferior to ordinary food.
- (f) The composition or characteristics of the food can be confirmed by appropriate test methods.

(B) Standard criteria

Foods for people with dysphagia should conform to the standards listed in Table 3.

If a food requires simple cooking such as heating, it is considered valid for people with dysphagia if its condition meets the applicable standards after being cooked as instructed.

Table 3

Standard <sup>*1</sup>	Permission Criteria I <sup>*2</sup>	Permission Criteria II <sup>*3</sup>	Permission Criteria III <sup>*4</sup>
Hardness (Resistance when compressed at a constant rate) (N/m <sup>2</sup> )	$2.5 \times 10^3$ $-1 \times 10^4$	$1 \times 10^3$ $-1.5 \times 10^4$	$3 \times 10^2$ $-2 \times 10^4$
Stickiness (J/m <sup>3</sup> )	$4 \times 10^2$ or less	$1 \times 10^3$ or less	$1.5 \times 10^3$ or less
Cohesiveness	0.2-0.6	0.2-0.9	—

\*1 Properties of a food should always be within the ranges of the standards, whether it is at room temperature or suitable temperature for eating.

\*2 Homogeneous foods such as jelly-like foods.

\*3 Homogeneous foods such as jelly- or mousse-like foods, excluding foods that conform to Permission Criteria I.

\*4 Including heterogeneous foods, such as highly cohesive rice porridge and soft paste-form or jelly-like foods. Excluding foods that conform to Permission Criteria I or II.

(2) Thickeners

Labeling permission for thickeners is granted to a food that conforms to the following criteria.

(A) Basic criteria

- (a) The food, when added to a liquid, is capable of controlling the properties of the liquid, and suitable from a medical and nutritional point of view for consumption by people with dysphagia who need special care.

- (b) The food has actually been taken by people with dysphagia.
- (c) The claim of the special uses of the food is appropriate for foods for people with dysphagia.
- (d) The food is easy to use.
- (e) The characteristics of the food can be confirmed by appropriate test methods.

(B) Standard criteria

Thickeners should meet the following viscosity and performance requirements.

In principle, thickeners adjusted are supposed to be used for homogeneous liquid. If they are intended to be used for liquid diet or heterogeneous liquid (e.g., miso soup), they should be accompanied by precautions.

(a) Viscosity requirements

Average viscosity (mPa·s)	100	400
Consistency* (%)	0.1 or more but less than 1.5	1.5 or more but less than 4.0

\* Consistency when added to distilled water

(b) Performance requirements

a. Solubility, dispersibility

The food prepared by the thickener does not contain a lump\* of insoluble matter of 5 mm or larger at 10°C, 20°C or 45°C.

b. Temporal stability

The viscosity of the food prepared by the thickener as determined 30 minutes after preparation, is within the range of ±15% of its viscosity 10 minutes after preparation.

c. Resistance to saliva

If amylase is added to the food prepared by the thickener, its viscosity as determined 30 minutes after preparation is not less than 75% of the food prepared without adding amylase.

d. Temperature stability

The viscosity of the food prepared by the thickener at 10°C and 45°C is within the range of ±35% of the viscosity at 20°C.

\* A lump is formed when the solution does not penetrate into the center of the object and only the surface of the object absorbs water, which shows insufficient swelling and hydration.

3. Labeling requirements

(1) Foods for people with dysphagia

If permission is granted for a food for people with dysphagia, the label must contain the following information.

- (A) Wording meaning "food for people with dysphagia"
- (B) A figure indicating the applicable category of permission criteria \*
- (C) Suitable temperature for eating
- (D) Weight per package

(E) Amounts of energy, protein, total fat, carbohydrates, and sodium (converted to salt intake equivalent) per package

(F) A statement that it is appropriate to use the food upon receiving advice from medical professionals, such as a physician, dentist, registered dietitian, pharmacist and speech-language therapist, and following their instructions

\* For the requirement in (B), any of Figures 1 to 3 should be displayed near the certificate of permit or certificate of approval.

Table 4

Category of permission Criteria	Description of category of permission Criteria
Permission Criteria I	Can be swallowed directly <sup>*1</sup>
Permission Criteria II	Can be swallowed after being mashed slightly in the mouth <sup>*2</sup>
Permission Criteria III	Can be swallowed after being chewed slightly <sup>*3</sup>

\*1 Homogenous jelly-like foods

\*2 Homogenous jelly, pudding or mousse-like foods

\*3 Heterogeneous foods, such as highly cohesive rice porridges

Notes can be displayed anywhere other than on the container or package.

Figure 1 Permission Criteria I

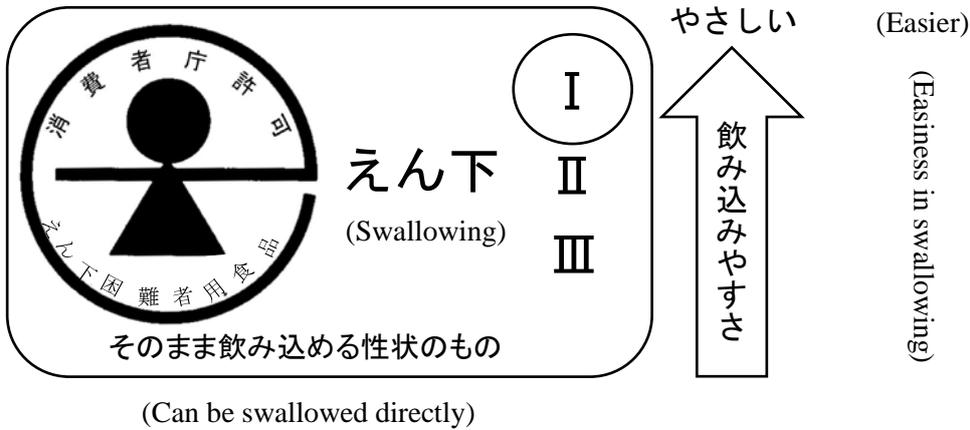


Figure 2 Permission Criteria II

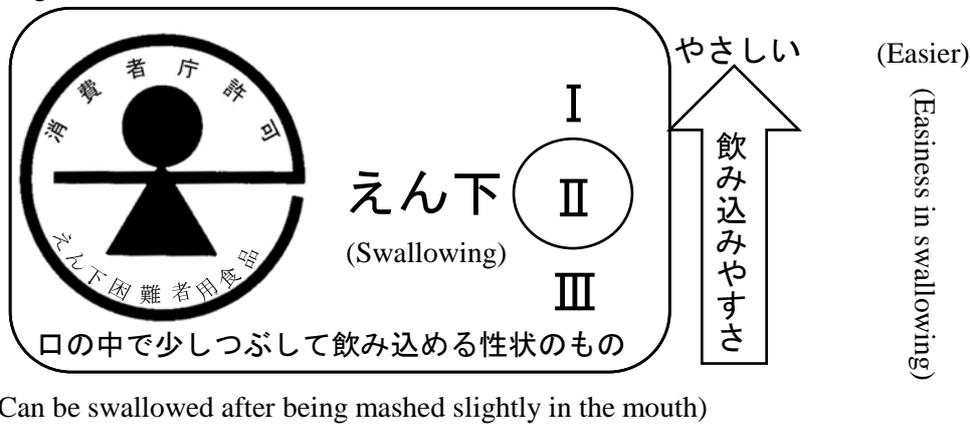
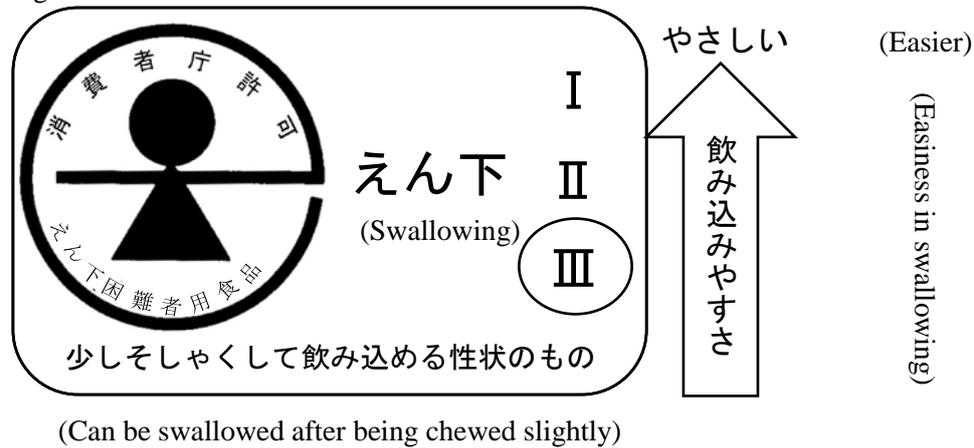


Figure 3 Permission Criteria III



(2) Thickeners

If permission is granted for a thickener, the label must contain the following information.

(A) Wording meaning "thickener"

(B) Amount per use (the standard amount to be used for thickening the major food should be specified.)

(C) Suitable temperature for eating and precautions concerning the difference in viscosity caused by

temperature difference (e.g., a statement that the agent is appropriate for thickening foods at 10°C to 45°C and that care should be taken to adjust the amount to be added depending on the difference in the temperature for eating)

(D) Weight per package

(E) Amounts of energy, protein, total fat, carbohydrates, and sodium (converted to salt intake equivalent) per use or per package

(F) A statement that it is appropriate to use the agent upon receiving advice from medical professionals, such as a physician, dentist, registered dietitian, pharmacist and speech-language therapist, and following their instructions

(G) Precautions concerning the foods to be thickened (e.g., the difference in viscosity caused by the difference in the type of food or the amount used)

(H) Procedure for adding the agent to the food (e.g., the speed and period of time of mixing the agent and food to adjust the viscosity at an appropriate level)

(I) Precautions for consuming the agent (e.g., the effect of the food temperature on the viscosity)

(J) Other necessary instructions

#### Section VI Indicated Value and Analysis Value

When determining the quantity of the contents in foods for special dietary uses, the analysis values of nutritional composition should be within the following ranges compared with the indicated values.

- (1) Energy, protein, total fat, carbohydrates, and sodium: 80–120%
- (2) Fat-soluble vitamins and minerals: 80–150%
- (3) Water-soluble vitamins and inositol: 80–180%
- (4) Others: 80–120%

If the analysis value of any nutritional composition cannot be kept within the above range for reasons such as the low content per 100 g, the value may be indicated by way of a range as long as it is based on scientific evidence (e.g., "mean  $\pm$  2 standard deviations"). The scientific evidence should be accompanied by supporting materials (including the explanation of the reasonable grounds for indicating the value by way of a range).

#### Section VII Matters for Applying for Labeling Permission for Foods for Special Dietary Uses

1. The application form and descriptions to be entered therein should comply with the provisions of Attachment 2 "Guidelines for Handling and Guidance on Foods for Specified Health Uses" of this Notification.

2. The following documents should be attached to the application form.

(1) A copy of articles of incorporation or endowment if the applicant is a corporate body

(2) Test reports

(A) A test report to certify the following:

- Foods for medical uses (Approval Criteria form): the food conforms to each item in the Standards

section of Annex 1 "Permission Criteria by Food Group."

- For powdered formulas for pregnant and lactating women and infant formulas: the food conforms to each item of the criteria for labeling permission.

- For foods for people with dysphagia (including thickeners): the food conforms to each item and requirement of the standard criteria among the criteria for labeling permission.

(B) In the case of an application regarding foods for medical uses (Individual Evaluation form): qualitative and quantitative test reports of participating nutrients in the food.

With regard to the analysis items for the tests mentioned in (A) and (B), as defined in Annex 2, at least three randomly selected product samples with different dates of manufacture or from different lots should be used for testing at research and development institutions established by the national or regional regulatory authorities or the like, or other institutions considered as appropriate, by the test method described in Annex 3. Each test report should include the name of the testing institution and the name of the tester and the seal affixed by the responsible person.

### (3) Label sample

An illustration of the container or package or the package insert to be used when selling the food should be submitted.

(4) Documents to objectively certify that the food conforms to the criteria or requirements for permission.

(A) Foods for medical uses (Approval Criteria form): documents to objectively certify that the food conforms to each item of the basic criteria and general criteria listed in Section II, 1 and 2.

Specifically, these documents include the following.

(a) Product specification of the food established by the manufacturer and test method to verify it

(b) History of the food from the beginning of production to date, and its record of sales

As sales results are necessary to evaluate the safety of the food, products without record of sales are excluded from the range of foods eligible for application for permission. However, this does not apply to products made by altering the flavors of a product that has a record of sales, provided that the identity of the product can be proven, and that documents to secure the safety of the food are provided.

(c) If the results of the use of the food have been reported by hospitals and other medical institutions, the relevant reports

Documents regarding the results of use should describe the record of the use of the food at hospitals and other medical institutions, such as that the food can be taken continuously on a daily basis, and should contain the results of questionnaire surveys targeted at patients, physicians, registered dietitians, and the like.

(B) Documents to objectively certify that the food conforms to the requirements regarding "Foods for medical uses (Approval Criteria form)" described in Section II, 3(2) should prove from a medical and nutritional point of view that the food can be used as an alternative to the conventional food consumed by patients in terms of the characteristics, purpose of use, and form of consumption.

(C) For Individual Evaluation form foods for patients: the following documents to objectively certify that the food conforms to the requirements described in Section II, 4(2), (A) to (G) and (J).

(a) Documents providing medical and nutritional evidence to show that the food or its participating nutrients are effective in diet therapy to cure a specific disease

a. Clinical data (clinical study results) are required to prove that the use of the food is helpful in diet therapy to cure the disease or prevent its recurrence or progression.

b. If the food has already been used as a part of diet therapy at hospitals and other medical institutions, and its effectiveness and usage in diet therapy have been medically and nutritionally proven, the primary clinical data to indicate such effectiveness should be attached to the application.

c. If the food is consumed generally but has not been used for diet therapy, data of comparative tests with a control group are required to prove the effectiveness of the food.

d. In any of the cases above, not only internal documents but also objective documents are required, such as papers published or scheduled to be published in academic journals after peer review.

(b) Documents necessary for medically and nutritionally establishing an appropriate usage of the food or its participating nutrients in diet therapy for patients

It is necessary to attach documents describing how to use the food in diet therapy, such as examples of practical use in nutrition guidance. However, if a document regarding the setting of the amount of intake is necessary in order to describe the usage, the basis for setting the amount of intake should be provided in the documents mentioned in (a).

(c) Documents to show that patients in diet therapy can take the food continuously on a daily basis

It is necessary to attach documents describing the record of the use of the food at hospitals and other medical institutions, such as that the food can be taken continuously on a daily basis, and those containing the results of questionnaire surveys targeted at patients, physicians, registered dietitians, and the like.

(d) Documents regarding the safety of the food or its participating nutrients

It is necessary to attach documents regarding safety issues such as toxicity and those explaining the development of allergies, if any, obtained through literature search.

(e) Documents regarding the stability of the food or its participating nutrients

It is necessary to attach documents necessary for describing the stability and setting the expiration date or best before date of the participating nutrients.

(f) Documents regarding the physical, chemical, and biological properties of the participating nutrients, and the test methods thereof

(g) Qualitative and quantitative test reports of the participating nutrients of the food and documents describing the test methods thereof

(h) If the food is identical with a food already granted permission in terms of the participating

nutrients, the details of the permitted label, the usage, and the form, it is not necessary to attach the full texts of the relevant documents but sufficient to attach the summaries thereof.

(D) For foods for people with dysphagia (including thickeners): documents to objectively certify that the food conforms to each item of the basic criteria as listed in Section V.

Specifically, these documents include the following.

(a) Product specification of the food specified by the manufacturer and test method to verify it

(b) History of the food from the beginning of production to date, and its sales results

As sales results are necessary to evaluate the safety of the food, products without record of sales are excluded from the range of foods eligible for application for permission. However, this does not apply to products made by altering the flavors of a product that has a record of sales, provided that the identity of the product can be proven, and that documents to secure the safety of the food in the application are provided.

(c) If the results of the use of the food have been reported by hospitals and other medical institutions, the relevant reports

Documents regarding the results of use should describe the record of the use of the food at hospitals and other medical institutions, such as that the food can be taken continuously on a daily basis, and should contain the results of questionnaire surveys targeted at patients, physicians, registered dietitians, and the like.

(5) Internal test results of the food

Internal test results should be reports of results of tests conducted by the manufacturer at its own test facility by testing the product specification set by the manufacturer for the food. A manufacturer that does not have its own test facility may conduct a test by using other appropriate testing institutions such as public research and development institutions mentioned in (2).

(6) Documents providing an overview of the structure and equipment of the manufacturing site and explaining the quality control method

With regard to the quality control method, it is necessary to explain the specification of the food set by the manufacturer (e.g., permission criteria, product specification, and nutrient declaration), the test method to verify the specification, and the test results, and to provide details such as that the manufacturer conducts tests via external testing institutions periodically, at least once a year, in addition to internal testing.

The conformity to the permission criteria and other requirements should be verified periodically at external testing institutions.

For infant formulas, it is necessary to attach documents certifying that the food has been approved by the Ministry of Health, Labour and Welfare under the provisions of the Ministerial Order on Milk. With regard to powdered and liquid milk for infants among foods for medical uses (especially allergen-free food products and lactose-free food products), it is necessary to attach documents to show that the food is subject to an equal level of sanitation control to that for infant formulas.

(7) Other general explanatory documents regarding the food

(8) A copy of a manufacturing subcontract agreement if the food is manufactured by a person other than the applicant

(9) Foods for medical uses (Individual Evaluation form): a list of attached documents in Form 1

3. A product sample should be submitted with the application form.

4. A prefectural governor (or a mayor of a city or special ward which has a public health center; the same applies hereinafter) who has received an application for permission for foods for medical uses (Individual Evaluation form) should inspect whether the submission of the required documents is complete by using Form 2 and forward appropriate applications to the Minister of the Consumer Affairs Agency.

#### Section VIII Addition of a New Category of Permission and Revision of the Existing Permission Criteria

1. A person who seeks the addition of a new category of food or revision of the existing permission criteria should submit a written request to the Food Labeling Division of the Consumer Affairs Agency (hereinafter referred to as the "Food Labeling Division"), with documents stating the following matters.

(1) Addition of a new category of food

(A) Necessity to add a new category of permission and the record of market sales

(B) Range of application of labeling (including details of the targeted consumers)

(C) Draft permission criteria based on safety evidence

(D) Evaluation methods required under the draft permission criteria (e.g., analysis methods and detailed measurement conditions)

(E) Draft Labeling requirements (e.g., labels and precautions required to enable consumers to choose and use the food properly)

(2) Revision of the existing permission criteria

(A) Necessity to revise the existing permission criteria (e.g., evidence of problems)

(B) Draft revision of the permission criteria (including safety evidence)

2. Procedure for examining the request

Upon receiving a request for the addition or revision, the Consumer Affairs Agency organizes a consultative body consisting of physicians, pharmacists, registered dietitians and the like (to meet annually in autumn, in principle) and makes a decision based on their opinions. If a particularly high level of expertise is required, the agency seeks opinions from other experts.

#### Section IX Effective Date and Transitional Measures

1. This Notification comes into effect as of the date of issue.

2. Notwithstanding the permission criteria under this Notification, prior criteria remain in force until March 31, 2020, with regard to the labeling permission for FOSDU which has been granted under the Health Promotion Act before this Notification comes into effect.

3. Notwithstanding the criteria regarding selenium set forth in Table 2 among the criteria for labeling

permission for infant formulas provided in Section IV of Attachment 1 of this Notification, prior criteria remain in force until March 31, 2022, with regard to infant formulas.

Section X            Others

With regard to the approval defined in Article 29, paragraph (1) of the Health Promotion Act, the provisions of Article 26, paragraphs (2) to (5) of the same Act apply mutatis mutandis pursuant to Article 29, paragraph (2) of the same Act, and accordingly, the provisions set forth in Sections I to IX above also apply mutatis mutandis.

Annex 1

Permission Criteria by Food Group

(1) Low-protein food products

Standards	Range of acceptable claims of special dietary uses	Labeling requirements
<ol style="list-style-type: none"> <li>1. The protein content should be not more than 30% of that of an ordinary food of the same kind.</li> <li>2. The energy should be equal to or more than those of an ordinary food of the same kind.</li> <li>3. The sodium and potassium contents should not be more than those of an ordinary food of the same kind.</li> <li>4. The food should be consumed continuously in daily meals as part of diet therapy* and can be an alternative to what has been consumed until now.</li> </ol>	<p>A statement that the food is suitable for patients with diseases requiring limited intake of protein (e.g., kidney diseases)</p>	<ol style="list-style-type: none"> <li>1. A statement that the food should be taken only when directed by a physician to limit intake of protein</li> <li>2. The protein content per fixed amount of product (for example, 1 unit or 1 piece)</li> <li>3. The amounts of energy, protein, total fat, carbohydrates, sodium (converted to sodium chloride equivalent), potassium, calcium, phosphorus, and other intentionally enhanced composition, per 100 g and per meal, package or any other unit</li> <li>4. Wording meaning "low protein"</li> <li>5. A statement that it is appropriate to take the food upon advice with a physician or registered dietitian and following their instructions</li> <li>6. A statement that the food is suitable as a part of diet therapy, and that high intake of the food does not lead to curing the disease</li> </ol>

\* A "food consumed continuously in daily meals" refers to not only foods people eat every day but also foods people eat frequently on a regular basis.

(2) Allergen-free food products

Standards	Range of acceptable claims of special dietary uses	Labeling requirements
<ol style="list-style-type: none"> <li>1. The food should be made free of specific allergens that are causative agents of specific food allergies by not using or by removing such allergens (or reducing them to below the detection limit).</li> <li>2. The contents of nutritional composition other than the removed allergens should be almost equal to those of an ordinary food of the same kind.</li> <li>3. The specific allergens should be below the detection limit when tested by a method used for foods containing allergens.</li> <li>4. The form of consumption of the food does not significantly differ from that of similar kinds of food.</li> </ol>	<p>A statement that the food is suitable for patients with specific food allergies (e.g., allergy to milk)</p>	<ol style="list-style-type: none"> <li>1. A statement that the food should be taken only when directed by a physician to limit intake of specific allergens</li> <li>2. The types of food allergies or names of removed allergens (in emphasized lettering)</li> <li>3. The names of the alternatives to the removed allergens</li> <li>4. The vitamin and mineral contents</li> <li>5. Standard usage</li> <li>6. A statement that it is appropriate to take the food upon receiving advice from a physician and registered dietitian and following their instructions</li> <li>7. A statement that the food is suitable as a part of diet therapy, and that high intake of the food does not lead to curing the disease</li> </ol>

(3) Lactose-free food products

Standards	Range of acceptable claims of special dietary uses	Labeling requirements
<p>1. The food should be made with lactose or galactose removed.</p> <p>2. The contents of nutritional composition other than the lactose or galactose should be almost equal to those of an ordinary food of the same kind.</p>	<p>A statement that the food is suitable for patients suffering from lactose intolerance or galactosemia</p>	<p>1. A statement that the food should be taken only when directed by a physician to limit intake of lactose or galactose</p> <p>2. The names of the alternative to lactose or galactose</p> <p>3. The vitamin and mineral contents</p> <p>4. Standard usage</p> <p>5. Wording meaning "lactose-free"</p> <p>6. A statement that the food contains milk protein, if applicable</p> <p>7. A statement that it is appropriate to take the food upon receiving advice from a physician and registered dietitian and following their instructions</p> <p>8. A statement that the food is suitable as a part of diet therapy, and that high intake of the food does not lead to curing the disease</p>

(4) Comprehensive nutrition food products

Standards	Range of acceptable claims of special dietary uses	Labeling requirements
<p>1. The food should be in liquid or semisolid form with appropriate fluidity as an alternative food for patients having difficulties in oral intake due to diseases.</p> <p>2. The food conforms to the criteria for nutritional composition defined in Appended Table 1.</p> <p>* (Powdered food products are considered valid if they conform to the standards 1 and 2 above after they are adjusted as instructed.)</p>	<p>A statement that the food is a comprehensive nutrition food product with well-balanced nutrients that need to be consumed in a meal and that it is suitable for patients with difficulties in taking sufficient nutrition from ordinary meals due to diseases</p>	<p>1. Wording meaning "comprehensive nutrition food product (for patients)"</p> <p>2. A statement that it is appropriate to take the food upon receiving advice from a physician and registered dietitian and following their instructions</p> <p>3. A statement that the food is suitable as a part of diet therapy, and that high intake of the food does not lead to curing the disease</p> <p>4. Information concerning instructions for taking the food</p> <p>5. A statement that the food contains composition adjusted beyond the criteria (Appended Table 1) and standard range (Appended Table 2), if it contains any such composition (indicated with wording meaning "XX adjusted")</p> <p>6. Energy per package</p> <p>7. The amounts of protein, total fat, carbohydrates, sugar, dietary fiber, sodium (converted to sodium chloride equivalent), and water per 1 package and 100 kcal, and the content of composition adjusted beyond the criteria (Appended Table 1) and standard range (Appended Table 2)</p> <p>8. A statement that the food contains composition that should not be lacked or taken excessively, if it contains any such composition</p>

\* This does not apply to individually adjusted composition.



Appended Table 1 (Criteria for nutritional composition)

	Energy per 100 ml (or 100 g)
Energy	80–130kcal

Composition	Composition per 100 kcal
Proteins <sup>*1</sup>	3.0–5.0g
Total fat <sup>*2</sup>	1.6–3.4 g
Sugar	50–74%
Dietary fiber	(as heat ratio)
Sodium	60–200 mg
Niacin	0.45 mgNE–15 <sup>*3</sup> (5 <sup>*4</sup> ) mg
Pantothenic acid	0.25mg or more
Vitamin A	28 µgRE–150µg retinol <sup>*5</sup>
Vitamin B <sub>1</sub>	0.04 mg or more
VitaminB <sub>2</sub>	0.05 mg or more
VitaminB <sub>6</sub>	0.06–3.0 mg
VitaminB <sub>12</sub>	0.12 µg or more
Vitamin C	5 mg or more
Vitamin D	0.3–2.5 µg
Vitamin E	0.4–30 mg
Vitamin K	3–13 µg
Folic acid	12–50 µg
Chlorine	50–300 mg
Potassium	80–330 mg
Calcium	33–115 mg
Iron	0.3–1. 8mg
Magnesium	14–62 mg
Phosphorus	45–175 mg

\*1 Consider amino acid score.

\*2 Combine essential fatty acids.

\*3 As nicotinamide

\*4 As nicotinic acid

\*5 Not including provitamin and carotenoid

Appended Table 2 (Standard range)

Composition	Composition per 100 kcal
Biotin	2.3 µg or more
Zinc	0.35–1.5 mg
Chromium	1–7 µg
Selenium	1–18 µg
Copper	0.04–0.5 mg
Manganese	0.18–0.55 mg
Molybdenum	1–12 µg
Iodine	8–120 µg

## Annex 2

Food group	Analysis items
Low-protein food products	Energy, protein, sodium, and potassium
Allergen-free food products	Energy, water, protein, total fat, carbohydrates, mineral content, sodium, and removed allergens
Lactose-free food products	Energy, water, protein, total fat, carbohydrates, mineral content, sodium, and lactose (or galactose)
Comprehensive nutrition food products	Energy, water, protein, total fat, sugar, dietary fiber, mineral content, sodium, salt equivalent, niacin, pantothenic acid, vitamin A, vitamin B <sub>1</sub> , vitamin B <sub>2</sub> , vitamin B <sub>6</sub> , vitamin B <sub>12</sub> , vitamin C, vitamin D, vitamin E, vitamin K, folic acid, chlorine, potassium, calcium, iron, magnesium, and phosphorus
Individual Evaluation form foods for patients	Participating nutrients (food ingredients that participate in curing a disease when diet therapy is conducted)
Powdered formulas for pregnant and lactating women	Energy, water, protein, total fat, carbohydrates (sugar and dietary fiber), mineral content, niacin, vitamin A, and vitamin B <sub>1</sub> , vitamin B <sub>2</sub> , vitamin D, and calcium
Infant formulas (Infant formula in powdered form and Infant formula in liquid form)	Energy, water, protein, total fat, carbohydrates, mineral content, niacin, pantothenic acid, biotin, vitamin A, vitamin B <sub>1</sub> , vitamin B <sub>2</sub> , vitamin B <sub>6</sub> , vitamin B <sub>12</sub> , vitamin C, vitamin D, vitamin E, folic acid, inositol, zinc, chlorine, potassium, calcium, iron, copper, selenium, sodium, magnesium, phosphorus, $\alpha$ -linolenic acid, linoleic acid, calcium/phosphorus ratio, and linoleic acid/ $\alpha$ -linolenic acid ratio
Foods for people with dysphagia	Hardness, stickiness, and cohesiveness
Thickeners	Viscosity, solubility, dispersibility, temporal stability, resistance to saliva, and temperature stability

## Annex 3

### 1. Test methods for foods for medical uses

(1) Unless otherwise specified, test methods for nutritional composition and inspection methods for foods for medical uses containing allergens follow the analysis methods for nutritional composition<sup>\*1)</sup> and inspection methods for foods containing allergens<sup>\*2)</sup> described in the Food Labeling Standards (Cabinet Office Order No. 10 of 2015).

(2) In the test report, identify the test methods used to determine nutritional composition of food samples when they differ from those specified in the test methods mentioned in (1).

### 2. Test methods for powdered formulas for pregnant and lactating women

Use the analysis methods for nutritional composition<sup>\*1)</sup> described in the Food Labeling Standards.

### 3. Test methods for infant formulas (in powdered and liquid form)

(1) Unless otherwise specified, use the analysis methods for nutritional composition<sup>\*1)</sup> described in the Food Labeling Standards.

(2) Measure chlorine using “potentiometric titration method” described in Appended Table 3.

(3) Measure inositol using “microbioassay” described in Appended Table 4.

(4) When quantification of selenium is difficult using the analytical methods described in the Food Labeling Standards, you may use “inductively coupled plasma mass spectrometry” described in Appended Table 5.

### 4. Test methods for foods for people with dysphagia (including thickeners)

(1) Test methods for foods for people with dysphagia (methods to test hardness, stickiness, and cohesiveness)

a) Place a precise amount of a sample in a circular container 40 mm in diameter and 20 mm in height so that it fills the container to the 15 mm level (a 15-mm-high container is acceptable if it will securely prevent the sample from spilling out). Apply compressive stress to the contained food sample using a texture analyzer equipped with a resin plunger (20 mm in diameter and 8 mm in height). Allow the plunger to move down into the sample at the speed of 10 mm/sec until it reaches 5 mm above the bottom of the container. During this process, allow the analyzer to measure the parameters related to hardness, stickiness, and cohesiveness of the sample. Take this measurement twice. For food intended to be served cold or at room temperature, adjust the temperature of the food samples to  $10 \pm 2^\circ\text{C}$  and  $20 \pm 2^\circ\text{C}$  during each measurement, and for food intended to be served warm, adjust the temperature to  $20 \pm 2^\circ\text{C}$  and  $45 \pm 2^\circ\text{C}$  (method A).

b) When testing a food appropriate for type I labeling and intended to be served cold or at room temperature, and the sample is inadequate to fill a 40-mm-diameter container, you may follow the alternative testing procedures described below.

Place a precise amount of a sample in a container 30 mm in diameter and 15 mm in height so that it fills the container to the top (ensure that the sample will not spill out of the container). Apply compressive stress to the contained food sample using a texture analyzer equipped with a resin

plunger (16 mm in diameter and 25 mm in height). Allow the plunger to move down into the sample at the speed of 10 mm/sec until it reaches 5 mm above the bottom of the container. During this process, allow the analyzer to measure the parameters related to hardness, stickiness, and cohesiveness of the sample. Take this measurement twice. Adjust the temperature of the food samples to  $10 \pm 2^\circ\text{C}$  and  $20 \pm 2^\circ\text{C}$  during each measurement (method B). Multiply the obtained hardness measurement value by 1.1, the obtained stickiness measurement value by 0.7, and the obtained cohesiveness measurement value by 1.2.\*<sup>3)</sup>

If you multiplied the measurement values obtained using method B by values other than those specified in b), you are required to provide verification of those values. You are also required to provide results of tests on food products concerned performed by a research institute or registered testing organization. Be sure to identify the specific multipliers used by the research institute/registered testing organization in the test report.

(2) Test methods for thickeners

(A) Viscosity

- 1) Pour an appropriate amount of distilled water (see the table below) into a 200-ml glass beaker. Adjust the temperature of the water to  $20 \pm 2^\circ\text{C}$  by placing the beaker in a thermostatic water tank.

Resulting concentration (%)	0.5	1.5	2.0	4.0
Distilled water (g)	99.5	98.5	98.0	96.0
Food sample (g)	0.5	1.5	2.0	4.0

- 2) Weigh a food sample placed on weighing paper.
- 3) Gradually add weighed food sample into the beaker over several seconds while stirring the distilled water at the rate of approximately three rotations per second using a 180-mm-long lab spatula. Continue stirring the mixture at the same rate for another 30 seconds.
- 4) Leave the beaker to stand in the thermostatic water tank ( $20 \pm 2^\circ\text{C}$ ) for 30 minutes.
- 5) Transfer the mixture into a cone and plate viscometer. Set the shear rate of the viscometer at  $50 \text{ s}^{-1}$ . Record the viscosity of the mixture after the viscometer was operated in a measurement mode for two minutes.

(B) Solubility and dispersibility

- 1) Pour 150.0 g of distilled water into a 200-ml glass beaker. Adjust the temperature of the water to  $20 \pm 2^\circ\text{C}$  by placing the beaker in a thermostatic water tank.
- 2) Weigh a food sample placed on weighing paper. The amount of the sample should meet the viscosity requirements for this test: its concentration in distilled water should be at least 1.5% and no more than 4.0% (w/w), and the viscosity of the mixture 30 minutes after it was added to distilled water should be  $400 \pm 20 \text{ mPa per second}$ .
- 3) Add all of the weighed food sample at once into the beaker while stirring the distilled water at

the rate of approximately three rotations per second using a 180-mm-long lab spatula. Continue stirring the mixture at the same rate for another 10 seconds. Leave the beaker to stand in the thermostatic water tank ( $20 \pm 2^\circ\text{C}$ ) for 20 seconds.

4) Visually inspect the presence of undissolved opaque masses 5 mm or greater in size in the mixture to complete the test.

5) Repeat this test two more times (a total of three times).

6) Perform similar tests two more times with the temperature of distilled water adjusted to  $10 \pm 2^\circ\text{C}$  and  $45 \pm 2^\circ\text{C}$ , respectively. Visually inspect the presence of undissolved opaque masses 5 mm or greater in size in the mixture. In the test at  $45 \pm 2^\circ\text{C}$ , you may choose to use a 300-ml glass beaker (instead of a 200-ml glass beaker) and stir back and forth (rather than circularly) at the rate of approximately two round trips per second.

#### (C) Stability over time

1) Pour 150.0 g of distilled water into a 200-ml glass beaker. Adjust the temperature of the water to  $20 \pm 2^\circ\text{C}$  by placing the beaker in a thermostatic water tank.

2) Weigh a food sample placed on weighing paper. The amount of the sample should meet the viscosity requirements for this test: its concentration in distilled water should be at least 1.5% and no more than 4.0% (w/w), and the viscosity of the mixture 30 minutes after it was added to distilled water should be  $400 \pm 20$  mPa per second.

3) Gradually add the weighed food sample into the beaker over several seconds while stirring the distilled water at the rate of approximately three rotations per second using a 180-mm-long lab spatula. Continue stirring the mixture at the same rate for another 30 seconds.

4) Leave the beaker to stand in the thermostatic water tank ( $20 \pm 2^\circ\text{C}$ ) for 10 minutes.

5) Transfer aliquots of the mixture into a cone and plate viscometer. Set the shear rate of the viscometer at  $50 \text{ s}^{-1}$ . Record the viscosity of the mixture after the viscometer was operated in a measurement mode for two minutes.

6) Place the beaker back in the thermostatic water tank ( $20 \pm 2^\circ\text{C}$ ). Leave the beaker to stand in the thermostatic water tank ( $20 \pm 2^\circ\text{C}$ ) for 20 minutes (30 minutes overall). Measure the viscosity of the mixture again, following the step in 5). Compare the two viscosity measurements.

#### (D) Resistance to saliva

1) After the completion of viscosity measurements for stability over time, divide the mixture into two 70.0 g masses (solutions I and II) and place them separately in 100-ml glass beakers.

2) In the next step described below, amylase will be added to solution II but not to solution I.

3) Cover the top of both beakers containing solutions I and II with aluminum foil. Leave the

beakers to stand in the thermostatic water tank adjusted to 37°C for one hour.

4) Remove the beaker containing solution II from the thermostatic water tank. Add 70 µl of an amylase solution (which had been adjusted to a 100 U/ml concentration in advance) to solution II using a micropipette. Stir the mixture at the rate of approximately three rotations per second for 10 seconds using a 180-mm-long lab spatula. Leave both beakers containing solutions I and II to stand in the thermostatic water tank adjusted to 37°C for 30 minutes.

5) Remove both beakers from the thermostatic water tank. Adjust the temperature of both solutions to  $20 \pm 2^\circ\text{C}$  by placing the beakers in the thermostatic water tank adjusted to  $20 \pm 2^\circ\text{C}$ .

6) Transfer one of the solutions into a cone and plate viscometer. Set the shear rate of the viscometer at  $50 \text{ s}^{-1}$ . Record the viscosity of the mixture after the viscometer was operated in a measurement mode for two minutes. Repeat the same procedure with the other solution.

(E) Temperature stability

1) Pour 150.0 g of distilled water into a 200-ml glass beaker. Adjust the temperature of the water to  $20 \pm 2^\circ\text{C}$  by placing the beaker in a thermostatic water tank.

2) Weigh a food sample placed on weighing paper. The amount of the sample should meet the viscosity requirements for this test: its concentration in distilled water should be at least 0.1% and no more than 1.5% (w/w), and the viscosity of the mixture 30 minutes after it was added to distilled water should be  $100 \pm 5 \text{ mPa per second}$ .

3) Gradually add the weighed food sample into the beaker over several seconds while stirring the distilled water at the rate of approximately three rotations per second using a 180-mm-long lab spatula. Continue stirring the mixture at the same rate for another 30 seconds.

4) Leave the beaker to stand in the thermostatic water tank ( $20 \pm 2^\circ\text{C}$ ) for 30 minutes.

5) Transfer the mixture into a cone and plate viscometer. Set the shear rate of the viscometer at  $50 \text{ s}^{-1}$ . Record the viscosity of the mixture after the viscometer was operated in a measurement mode for two minutes.

6) Repeat this measurement two more times by placing the beaker in a thermostatic water tank adjusted to  $10 \pm 2^\circ\text{C}$  for the second measurement and  $45 \pm 2^\circ\text{C}$  for the third measurement. Check the three viscosity measurements.

(3) Test methods for quantification of nutritional composition and energy

Use analysis methods for nutritional composition<sup>\*1)</sup> described in the Food Labeling Standards.

[Notes]

1) See the Attachment to “Notification regarding food labeling standards” (Shou-Shoku-Hyou No. 139, March 30, 2015), entitled “Analysis methods for nutritional composition.”

- 2) See the Attachment to “Notification regarding food labeling standards” (Shou-Shoku-Hyou No. 139, March 30, 2015), entitled “Inspection methods for foods containing allergens.”
- 3) If a product you intend to test is similar to another food product in terms of composition and manufacturing process, you may use different multipliers than those specified here. This requires the product to be placed in a container suitable for food texture measurements. You then need to perform food texture analysis using both methods A and B. Finally, you need to compare results between the two methods to justify the use of different multipliers.

## Appended Table 3

### Potentiometric titration method

#### 1. General procedure

Acidify a solution containing chlorine ions using nitric acid. Add silver solution to it. Using a silver electrode, measure changes in the electric potential of the solution with the increase in amount of silver chloride produced in the solution. Determine the titration end point by examining the potentiometric titration curve. Calculate the chloride concentration.

#### 2. Equipment

- (1) Automatic potentiometric titrator
- (2) 100-ml beakers
- (3) 1,000-ml measuring flasks
- (4) No. 7 filter paper
- (5) Chemical balance capable of reading to 0.1 mg

#### 3. Reagents

Use special grade reagents unless otherwise specified.

- (1) 0.01 mol/L sodium chloride standard solution

Dry sodium chloride by heating it at 130°C for 3 hours. Accurately measure 0.5844 g of dried sodium chloride and dissolve it in water to a total volume of 1,000 ml.

- (2) 0.01 mol/L silver nitrate solution

Accurately measure 1.7 g of silver nitrate and dissolve it in water to a total volume of 1,000 ml.

Determination of 0.01 mol/L silver nitrate solution multiplier factor (F)

Accurately measure 5 ml of 0.01 mol/L sodium chloride solution and place it in a 100-ml beaker. Add approximately 50 ml of water to the beaker. Add 1.5 ml of nitric acid and 5 drops of an electrolytic solution compatible with a chloride counter. Place a stirring bar in the beaker. Titrate the solution by adding a 0.01 mol/L silver nitrate solution using the automatic potentiometric titrator. Determine the titration end point A in ml.

$$F = \frac{5}{A}$$

- (3) Nitric acid

#### 4. Procedure

- (1) Preparation of a test solution<sup>Note</sup>

Accurately measure 0.1-10 g of sample (containing approximately 1 mg of chlorine) and place it in a 100-ml beaker. Add water to dissolve the sample, adjusting the total volume to 50-60 ml. Add 1.5 ml of nitric acid to complete a test solution.

- (2) Automatic potentiometric titrator requirements

- a) Indicator electrode: Suitable for measuring chlorides (e.g., silver electrode)
- b) Reference electrode: Suitable for measuring chlorides (e.g., mercurous sulfate electrode)

c) Burette: 20-ml brown burette

d) Titrant: 0.01 mol/L silver nitrate solution

(3) Measurement and calculation

Place a stirring bar in the beaker containing a test solution. Set the beaker on the automatic potentiometric titrator and start titrating. The titrator automatically calculates the chlorine content of the sample if the amount of the sample to be used is provided to it in advance.

Equation

$$\text{Chlorine (mg/100 g)} = \frac{0.3545 \times A \times F \times 100}{W}$$

A: End-point titer (ml)

F: 0.01 mol/L silver nitrate solution multiplier factor

W: Sample amount used (g)

0.3545: Chlorine content (in mg) of 1 mL of a 0.01 mol/L silver nitrate solution

[Note] When the pH of a test solution is neutral, the electric potential of the test solution changes as amino acids, proteins, and organic acids in it react with silver ions in the titrant. Ensure that the pH of the test solution is 3 or lower using pH papers.

## Appended Table 4

### Microbioassay

#### 1. Reagents

- Inositol standard solution (example): Dissolve 50 mg of inositol in 25% (v/v) ethanol solution to prepare exactly 200 ml of a solution. Dilute the solution to 5 µg/ml by adding water.
- Yeast species and strain: *Saccharomyces cerevisiae* (ATCC 9080)
- Culture medium for the measurement of inositol (for 1-L medium, pH = 5.0 ± 0.1)
  - Casamino acid, 10 g
  - Pyridoxine hydrochloride, 500 µg
  - Thiamine hydrochloride, 500 µg
  - Calcium pantothenate, 5 mg
  - Biotin, 50 µg
  - Potassium chloride, 850 mg
  - Glucose, 100 g
  - Calcium chloride, 250 mg
  - Magnesium sulfate, 250 mg
  - Manganese sulfate, 5 mg
  - Potassium dihydrogenphosphate, 1.1 g
  - Ferric chloride, 5 mg
  - Potassium citrate, 10 g
  - Citric acid, 2 g
  - Ammonium sulfate, 7.5 g

Commercial culture media products for the measurement of inositol are available <sup>Note 1)</sup>

- Yeast storage medium (for 1-L medium, pH = 5.0 ± 0.1)
  - Peptone, 5g
  - Yeast extract, 3 g
  - Glucose, 10 g
  - Carrageenan, 3 g
  - Malt extract, 3 g
- Pre-culture medium: Same as the yeast storage medium
- For other reagents not mentioned above, use special grade reagents unless otherwise specified.

#### 2. Preparation of inoculum suspension

Inoculate a pre-culture medium with a stored *Saccharomyces cerevisiae* strain and incubate it at 30°C for approximately 20 hours. Prepare an inoculum suspension by removing a loopful of cultured yeast from the medium using a platinum loop and adding it to sterile physiological saline. Add extra sterile physiological saline to adjust the concentration of the suspension to the target concentration, allowing 80-90% transmittance at 600 nm.

### 3. Preparation of test solution

Accurately measure 0.5-1 g<sup>Note 2)</sup> of the sample. Add 25 ml of 18% hydrochloric acid to the sample. Heat the mixture under reflux for 6-20 hours. After cooling, filter the mixture and remove hydrochloric acid from it by performing vacuum distillation. Dissolve the mixture in water. Adjust the pH of the solution to 5.0-6.0 by adding 10 mol/L sodium hydroxide. Add water to adjust the volume of the solution to exactly 100 ml. Filter the solution. Add water to dilute the concentration of the solution to the calibration curve range, completing the test solution.

### 4. Measurement

Preparation of test solutions. Accurately pour 0.5, 1, and 2 ml of the test solution into two test tubes each. Add 2.5 ml of the culture medium for the measurement of inositol and an appropriate amount of water to each test tube so that the content of all test tubes amounts to 5 ml.

Preparation of reference solutions. Add various amounts of the inositol standard solution (e.g., equivalent to 0-7.5 µg) to test tubes (two test tubes for each amount). Add 2.5 mL of the culture medium for the measurement of inositol and an appropriate amount of water<sup>Note 3)</sup> to each test tube so that the content of all test tubes amounts to 5 ml.

Determination of calibration curve. Autoclave the test tubes at 121°C for 5 minutes. After cooling, add a drop (approximately 30 µl) of inoculum suspension to each test tube under sterile conditions. Incubate the test tubes at 30°C on a shaker for approximately 20 hours. Quantify the growth of the culture by measuring the turbidity of the test tube content at 600 nm. Construct a calibration curve based on the turbidity data.<sup>4)</sup> Finally, determine the inositol content of the test solution by comparing turbidity between the test solution and the curve.

[Notes]

1) Inositol assay medium [Difco]

2) You may change the amount of a sample to be used in relation to the concentration of a target component, given that the sample is homogeneous and the change was confirmed to be scientifically appropriate beforehand.

3) Before preparing test solutions, study the correlation between the concentration of a standard solution and the growth of *S. cerevisiae*. In addition, determine the concentration range of the standard solution in which this correlative relationship is apparent. You may change the concentration of the solution as needed.

4) You may use a microplate and its reader to measure the turbidity of solutions. When using them, you may need to adjust the concentration of reference and test solutions.

## Appended Table 5

### Inductively coupled plasma mass spectrometry

#### 1. Equipment

- Inductively coupled plasma mass spectrometer (ICP-MS): You may use any general ICP-MS.
- Microwave digestion system: You should use a device equipped with internal temperature sensors and with temperature controlling functions. Your device should be equivalent in performance to Ethos 1 manufactured by Milestone General K.K.

#### 2. Reagents

- Nitric acid: Required to be extremely high purity with its metal content no more than 100 pg/ml. Its purity should be at least that of Ultrapur-100 of Kanto Chemical Co., Inc.
- Acetic acid: Required to be suitable for precision analysis.
- Hydrogen peroxide: Required to be special grade.
- Polyoxyethylene (10) octylphenyl ether: Required to be equivalent in grade to Triton X-100.  
The grade of all reagents above should be at least equivalent to those of mentioned products.
- Selenium standard solution: Prepare this by diluting a commercial selenium standard solution for atomic absorption spectrophotometry with ion exchange water to the concentration of 1 µg/ml.<sup>Note 1)</sup> Store the solution in a polyethylene or polypropylene bottle.
- Tellurium internal standard solution: Prepare this by diluting a commercial tellurium standard solution for atomic absorption spectrophotometry with ion exchange water to the concentration of 2 µg/ml. Store the solution in a polyethylene or polypropylene bottle.
- 1% surfactant solution: Add 99 g of ion exchange water to 1 g of polyoxyethylene (10) octylphenyl ether and mix.
- Standard solution for Se measurement (a. for microwave digestion): Place 10-500 µl of 1 µg/ml selenium standard solution in a polyethylene or polypropylene bottle. Add 5 ml of nitric acid, 1 ml of acetic acid, and 500 µl of 2 µg/ml tellurium internal standard solution to the bottle. Adjust the total volume to 50 ml (selenium concentration of 0.2-10 ng/ml<sup>Note 1)</sup>) by adding a precise amount of ion exchange water.
- Standard solution for Se measurement (b. for surfactant dilution method): Place 10-500 µl of 1 µg/ml selenium standard solution in a polyethylene or polypropylene bottle. Add 5 ml of 1% surfactant solution, 1 ml of acetic acid, and 500 µl of 2 µg/ml tellurium internal standard solution to the bottle. Adjust the total volume to 50 ml (selenium concentration of 0.2-10 ng/ml<sup>Note 1)</sup>) by adding a precise amount of ion exchange water.

#### 3. Preparation of test solution

Choose one of the two test solution preparation methods described below.

##### (1) Microwave digestion

Before performing this procedure, clean the microwave digestion container with a diluted nitric acid solution. Place 2 ml ( $V_1$ ) of a sample in the container. Add 5 ml of nitric acid and 1 ml of

hydrogen peroxide and seal the container. Perform microwave digestion under the conditions specified in the table below. After the digested sample has cooled, add 1 ml of acetic acid and 500 µl of a tellurium internal standard solution. Adjust the total volume to 50 ml (V<sub>2</sub>) by adding a precise amount of ion exchange water.

<Microwave digestion procedure example>

Step	Time (min)	Temperature (C)	Power (W)
1	2	70	0→1,000
2	3	50	0
3	25	50→200	0→1,000
4	10	200	1,000

(2) Surfactant dilution method

Place 2 ml (V<sub>1</sub>) of a sample in a polyethylene or polypropylene bottle. Add 5 ml of a surfactant solution to the bottle and mix. Add 1 ml of acetic acid and 500 µl of a tellurium internal standard solution. Adjust the total volume to 50 ml (V<sub>2</sub>) by adding a precise amount of ion exchange water.

4. Measurement

Determine the ion count ratio between selenium and internal standard substances in the standard solution for Se measurement using ICP-MS. Construct a calibration curve based on the concentration of the standard solution. Using the same procedure, determine the comparable ion count ratio in the test solution. Finally, determine selenium concentration C (in ng/ml) in the test solution by comparing the ion count ratio between the test solution and the calibration curve.

<Example of ICP-MS measurement settings>

Model	NexION 300D (PerkinElmer Inc.)
Supply speed	0.4 ml/min
Plasma generation parameters	Plasma output: 1.6 kW, plasma gas (argon) supply rate: 18 L/min, nebulizer gas (argon) flow rate: 1.0 L/min, auxiliary gas (argon) flow rate: 1.2 L/min
Nebulizer	Standard nebulizer
Atomic mass measurement	Selenium-82 (tellurium-128 as an internal standard) <sup>Note 2)</sup>
Gas mode	No-gas mode <sup>Note 2)</sup>

5. Calculation

Equation

$$\text{Selenium content of the sample } (\mu\text{g}/100 \text{ ml}) = \frac{C \times F \times V_2}{V_1 \times 10}$$

C: Selenium concentration (ng/ml) determined using the calibration curve

F: Standard solution multiplier factor

V<sub>1</sub>: Sample amount used (ml)

V<sub>2</sub>: Amount of sample solution (ml)

[Notes]

1) The lower limit value may vary for different devices.

2) If you choose to use a helium gas mode, atomic mass measurement should target selenium-78 (tellurium-128 as an internal standard).

List of documents to be attached

1. Label sample
2. Documents providing medical and nutritional evidence to show that the food or its participating nutrients are effective in diet therapy to cure a specific disease
3. Documents necessary for medically and nutritionally establishing an appropriate usage of the food or its participating nutrients in diet therapy for patients
4. Documents to show that patients in diet therapy can take the food continuously on a daily basis
5. Documents regarding the safety of the food or its participating nutrients
6. Documents regarding the stability of the food or its participating nutrients
7. Documents regarding the physical, chemical, and biological properties of the participating nutrients, and the test methods thereof
8. Qualitative and quantitative test reports of the participating nutrients of the food and documents describing the test methods thereof
9. Test reports of the amounts of nutritional composition and energy
10. A copy of articles of incorporation or endowment
11. Documents providing an overview of the structure and equipment of the manufacturing site and explaining the quality control method
12. A copy of a manufacturing subcontract agreement if the food is manufactured by a person other than the applicant
13. If any of these documents is considered not necessary to be attached, a document providing reasonable grounds therefor.

This format should be Japanese Industrial Standard (JIS) A4 size.

Form 2 (Re: Section VII, 4)

Application Form Checklist

Items to check	Check
1. Application Form for Labeling Permission for FOSDU (with revenue stamps affixed)	
(1) Name, address and date of birth of the applicant (if the applicant is a corporate body, its name, location of its principal office, and name of its representative)	
(2) Name and location of the business office (provide the name and location of the manufacturing site)	
(3) Product name	
(4) Expiration date or best before date	
(5) Ratio of combination of raw materials	
(6) Manufacturing method	
(7) Reason for seeking permission	
(8) Details of the label for which permission is sought	
(9) Amounts of nutritional composition and energy	
(10) Precautions for the method of intake, cooking, or storage which requires special attention	
(11) Labeling method	
(12) List of attached documents	
2. Product sample	
3. Label sample	
4. Documents providing medical and nutritional evidence to show that the food or its participating nutrients are effective in diet therapy to cure a specific disease	
5. Documents necessary for medically and nutritionally establishing an appropriate usage of the food or its participating nutrients in diet therapy for patients	
6. Documents to show that patients in diet therapy can take the food continuously on a daily basis	
7. Documents regarding the safety of the food or its participating nutrients	
8. Documents regarding the stability of the food or its participating nutrients	
9. Documents regarding the physical, chemical, and biological properties of the participating nutrients, and the test methods thereof	
10. Qualitative and quantitative test reports of the participating nutrients of the food and documents describing the test methods thereof	
11. Test reports of the amounts of nutritional composition and energy	
12. A copy of articles of incorporation or endowment	
13. Documents providing an overview of the structure and equipment of the manufacturing site and explaining the quality control method	
14. A copy of a manufacturing subcontract agreement if the food is manufactured by a person other than the applicant	
15. If any of these documents is considered not necessary to be attached, a document providing reasonable grounds therefor.	

Name of prefecture/city/ward: ( )

Name of public health center: ( )

Name of inspector:

Job title and job classification:

This format should be Japanese Industrial Standard (JIS) A4 size.

## Attachment 2

### Guidelines for Handling and Guidance on Foods for Specified Health Uses

#### 1. Purpose

These guidelines provide for handling and guidance regarding operations with respect to permission or approval for labeling for Foods for Special Dietary Uses under Article 26 or Article 29 of the Health Promotion Act (Act No. 103 of 2002; hereinafter referred to as the "Act").

#### 2. Label indicating suitability for a special use

(1) A label indicating suitability for a special use is a label stating with medical and nutritional expressions that the labeled food is suitable to be used for the growth or the maintenance or recovery of the health of infants, small children, pregnant women, patients and the like, and specifying its limitations of use.

(2) Labels simply indicating "For infants," "For small children" or the like do not require permission or approval.

#### 3. Labeling

##### (1) Definition of labeling

Labeling refers to displaying words, figures and the like on the container or package for the retail of foods. Displaying words, figures and the like that are printed inside the container or package but can be seen through from outside, and those printed on package inserts for foods is deemed to be labeling.

Displaying words, figures and the like on wrapping paper or bags used when selling foods, inner packages of foods, and advertisements, pamphlets and the like is not considered to constitute labeling.

##### (2) Information indicated on a label

###### (A) Product name

The exact product name as permitted or approved for labeling shall be displayed.

###### (B) The expiration date or best before date, storage method, location of the manufacturing site, and name of the manufacturer

These items of information shall be displayed properly according to the Food Labeling Standards.

###### (C) Certificate of permit or certificate of approval

The certificate of permit in Appended Form 2 of the Cabinet Office Order or certificate of approval in Appended Form 5 of the Cabinet Office Order shall be displayed.

###### (D) Details of the permitted or approved label

The details of the label shall be displayed as described in the column for "Details of the label for which permission (or approval) is sought" in the application form for permission or approval, paying careful attention to the following.

(a) No part of the permitted or approved label shall be omitted.

(b) The label shall not mislead consumers.

(c) Specific conditions set for granting permission or approval shall be observed, if there are any such conditions.

(E) Amounts of nutritional composition and energy

The amounts of nutritional composition and energy shall be displayed according to the Food Labeling Standards and based on the results of analysis conducted by a testing institution. The amounts of any indications not defined in Appended Table 9 of the Food Labeling Standards shall be specified in the space outside the section for displaying the nutrient declaration.

(F) Names of raw materials and additives

These items shall be displayed according to the Food Labeling Standards.

(G) Precautions for the method of intake, cooking, or storage which requires special attention

The information entered in the application form for permission or approval shall be displayed.

(H) If the person who holds permission or approval is not the manufacturer, the name and the location of the business office of the person (if the person is a corporate body, its name) shall be displayed.

(a) When displaying the address of the person who holds permission or approval, it is necessary to indicate the full address including the residence number according to the indication of residential address under the Act on Indication of Residential Address (Act No. 119 of 1962).

(b) If the applicant is an importer, this shall be stated and the name and address of the applicant shall be indicated.

(I) Other

The Food Sanitation Act (Act No. 233 of 1947) and other related laws and regulations shall be complied with.

(3) Handling of labels, etc.

(A) False or misleading statements shall not be used in labels or advertisements.

In the case of infant formulas, in order to avoid causing contradiction with the statement that breast milk is best for infants, any texts, illustrations, photographs or the like that could mislead people to believe that the labeled product is best for infants shall be avoided.

(B) To avoid the risk of violating the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices (Act No. 145 of 1960), the efficacy or effect similar to that of pharmaceuticals shall not be indicated on the container or package, package insert, advertisements, pamphlet or the like.

(C) The words used in the label shall conform to the Food Labeling Standards.

(D) The items of information set forth in 3(2) shall be displayed in a manner that makes them easy to read, such as displaying them collectively (hereinafter referred to as "collective labeling"). Collective labeling may be conducted in the following manner.

(a) Indicate the names of items in a simple form as follows.

a. Indicate "Details of the permitted label" with wording meaning "Permitted label."

b. Indicate "Precautions for the method of intake, cooking, or storage which require special attention" with wording meaning "Precautions for the method of intake, cooking, or storage."

c. Indicate "If the person who holds permission or approval is not the manufacturer, the name and the location of the business office of the person (if the person is a corporate body, its name)" with wording meaning "Manufacturer" or "Holder of Permission."

(b) Indicate the product name, the statement that the food is for special dietary uses, and the certificate of permit or approval in an easily visible section of the label separately from the section for collective labeling.

(c) If there is no information to be displayed, displaying information including the names of the items may be omitted.

#### 4. Points to note upon making an application for permission or approval

(1) An application for permission should be made by using Attached Form 1 and an application for approval should be made by using Attached Form 2, and by filling in the form completely, paying due attention to the following points to note.

(A) Name, address and date of birth of the applicant (if the applicant is a corporate body, its name, location of its principal office, and name of its representative)

(B) Name and location of the business office

The name and location of the principal business office should be indicated and accompanied by a note to provide the name and location of the manufacturing site.

(C) Product name

In the case of products of the same food, separate applications for permission or approval should be made if they have different product names.

(D) Expiration date or best before date

It is necessary to clearly state that the date indicated on the label is the expiration date if the quality of the food is likely to deteriorate quickly when stored as instructed, or that it is the best before date in the case of other products. How the expiration date or best before date is set should also be described.

(E) Ratio of combination of raw materials and additives

(a) It is necessary to indicate the names and amounts of all raw materials and additives used to manufacture the product, and the weight of the product manufactured with these materials and additives in the indicated amounts.

(b) The generic terms, not product names, should be used when indicating the names of the raw materials and additives. The method specified in the Food Labeling Standards should be applied with regard to the names of additives. The names of additives used for nutrition enhancement should also be indicated.

(c) With regard to additives subject to the criteria for use provided under the Food Sanitation Act, their purity and other measures should be indicated in order to confirm the compliance with the criteria.

(F) Manufacturing method

It is necessary to specify the manufacturing method and indicate manufacturing conditions in detail, such as the timing of adding vitamins during the processing and the heating temperature after addition.

(G) Reason for seeking permission

The reason why the food is suitable for the special use should be specified.

(H) Details of the label for which permission is sought

(I) Amounts of nutritional composition and energy

The amounts of nutritional composition and energy should be displayed properly according to the Food Labeling Standards and based on the results of analysis conducted by a testing institution.

(J) Precautions for the method of intake, cooking, or storage which requires special attention

(K) Labeling method

The labeling method regarding the expiration date or best before date, the location of the manufacturing site, the name of the manufacturer and other information should be described in accordance with the Food Labeling Standards.

(2) The following documents should be attached to an application form.

(A) A copy of articles of incorporation or endowment if the applicant is a corporate body

(B) Test reports regarding the amounts of nutritional composition and energy of the food

Each test report should include the name of the testing institution and the name of the tester and the seal affixed by the responsible person.

(C) Label sample

An illustration of the container or package or the package insert to be used when selling the food should be submitted.

(3) Submission of an application form

(A) An application form for permission: one set of original copy and duplicate copy of the application form should be submitted to the prefectural governor who has jurisdiction over the location of the principal business office.

(B) An application form for approval: one original copy should be submitted directly to the Food Labeling Division.

(C) Among the fees required for labeling permission or approval, those due to be paid to the National Treasury should be paid by affixing revenue stamps in an amount equivalent to the amount set forth in Article 3, item (i) of the Enforcement Order of the Health Promotion Act (Cabinet Order No. 361 of 2002) to the original copy of the application form for permission. A seal or the like should not be put on the revenue stamps affixed to the application form.

(4) Forwarding of an application form for permission

(A) The prefectural governor who received an application form for permission should inspect whether the submission of the application form is complete in light of the points to note indicated in 4(1), and forward one original copy of appropriate application form to the Minister of the

Consumer Affairs Agency using Attached Form 3.

(B) Upon finding any deficiency in the content of the application form for permission, the prefectural governor must return the application form to the applicant promptly, stating the reasons therefor.

(5) Testing of a product sample

(A) There is risk of a considerable gap in the technique for adding nutritional composition between the trial production on a small scale and the mass-production intended for the sale on the market. Therefore, an application for labeling permission should not be made in the trial stage but it should be accompanied by a product sample that is manufactured according to the combination of materials and manufacturing method applicable to the product intended for the sale on the market, and that is put in the container or package to be used for the sale on the market.

(B) For testing purposes, the applicant should bring the product sample directly to the National Institutes of Biomedical Innovation, Health and Nutrition (hereinafter referred to as "NIBIOHN") or a testing institution registered by the Commissioner of the Consumer Affairs Agency (hereinafter referred to as a "registered testing institution"), with a copy of the application form for permission, following the consultation with the Food Labeling Division. When requesting a test, the applicant should pay the amount set forth in Article 3, item (ii) of the Enforcement Order of the Health Promotion Act if the request is made to NIBIOHN, or the amount set forth in the operational rules for testing referred to in Article 26-8, paragraph (2) of the Act if the request is made to a registered testing institution, respectively.

The analysis items for testing at NIBIOHN or a registered testing institution should be as set forth in Annex 2 of Attachment 1. A request for testing should be made by the method specified by NIBIOHN or registered testing institution.

(C) The original copy of a test report issued by NIBIOHN or registered testing institution should be submitted to the Director of the Food Labeling Division.

5. Issue of labeling permit and labeling approval

(1) If permission is granted for labeling for FOSDU, a labeling permit in Attached Form 4 is sent to the prefectural governor who forwarded the application form, and that prefectural governor issues the permit to the applicant.

(2) If approval is granted for labeling for FOSDU, a labeling approval in Attached Form 5 is directly issued to the applicant.

6. Handling after the grant of permission

(1) Notification of changes, etc.

(A) Notification of changes

If any of the following changes occurs with regard to the food covered by the permission or approval, a notification of changes in Attached Form 6 should be submitted to the Food Labeling Division via the prefectural governor (in the case of permission) or directly (in the case of approval).

If there is a change to any of the obligatory information for labeling indicated on the label on the container or package, the label sample should be attached to the notification.

(a) A change to the name or address of the applicant (in the case of a corporate body, its name or the location of its principal office) within the extent that the applicant's identity as an individual or corporate body can be maintained

It is necessary to attach the articles of incorporation or any other document clearly showing that the change is appropriate.

(b) A change to the location of the manufacturing site or the name of the manufacturer (in the case of a corporate body, the name or the location of its principal office) if there is no change with regard to the holder of permission

It is necessary to attach a manufacturing subcontract agreement and documents concerning the structure and equipment and quality control at the manufacturing site after the change.

(c) A change to the expiration date or best before date

It is necessary to attach a stability test report based on the expiration date or best before date after the change.

(d) A change to the ratio of combination of raw materials or the manufacturing method within the extent that the identity of the product can be maintained

It is necessary to attach documents explaining the reasons for the change and the reasons why the product's identity can be maintained after the change, with scientific evidence thereof, and a test report on the amounts of nutritional composition and energy, aging test report and variation test report based on the tests conducted by public research and development institutions.

(e) Addition to precautions for the method of intake, cooking, or storage which requires special attention

It is necessary to attach a document explaining the reasons for the addition and evidence thereof

(f) A change to information indicated on the label other than obligatory information for labeling

If there a change to any of the information indicated on the label other than obligatory information for labeling, the label sample should be attached.

#### (B) Notification of invalidity

If any of the following causes occurs with regard to the food covered by the permission or approval, a notification of invalidity in Attached Form 7 should be submitted to the Food Labeling Division via the prefectural governor (in the case of permission) or directly (in the case of approval), while attaching the labeling permission or labeling approval.

(a) The individual who holds the permission or approval dies or the corporate body which holds the permission or approval is dissolved

In this case, a notification of invalidity should be made by an heir of the holder of permission or approval, or by a person who administers the estate on behalf of the heir, or by a liquidator, a bankruptcy trustee, or the representative of a corporate body surviving after a merger or

incorporated by a merger regarding the holder of permission or approval.

(b) The holder of permission or approval discontinues the sale or manufacturing of the product

## (2) Reapplication

An application for permission or approval should be made again in the following cases.

(A) To change the product name, except when there are truly compelling reasons for the change and no particular problem is found with the change.

(B) To change any of the details of the permitted or approved label

(C) To change the ratio of combination of raw materials or the manufacturing method beyond the extent that the product's identity can be maintained

## 7. Preliminary consultation for making an application, etc.

The Food Labeling Division provides preliminary consultation services as needed. Inquiries are acceptable from those who intend to make an application for permission, a notification of changes, etc., and reapplication with regard to labeling for foods for special dietary uses.

## 8. Periodic reporting on quality control

The results of a periodic test conducted by an external testing institution with regard to the food covered by the permission or approval should be compiled into a quality control report in Reference Form 3, and submitted in June each year to the Food Labeling Division via the prefectural governor (in the case of permission) or directly (in the case of approval), while attaching a copy of the test report issued by the external testing institution by that time (on which the name of the testing institution and the name of the tester are indicated and to which the seal of the responsible person is affixed) and documents showing the status of quality control and conformity to the permission criteria (in the case of infant formulas, powdered and liquid milk for infants among foods for patients, and comprehensive nutrition food products, the test results per 100 kcal which show the conformity to the permission criteria should also be attached).

## 9. Instructions to persons who intend to obtain permission or approval

Provide instructions on the following points to persons who intend to obtain permission or approval.

(1) Ensure that the addition of nutritional composition will not have any adverse effect on the quality, etc. according to the characteristics of each food.

(2) Ensure that quality control of products is performed sufficiently and a continuous monitoring system to prevent defective products is set in place.

(3) If it is uncertain whether the label in an application meets the current permission requirements, make inquiries to the Food Labeling Division.

## 10. Monitoring and guidance

When conducting monitoring on foods for special dietary uses, please pay attention to the following points.

(1) In enforcing guidance and regulations in relation to food labeling, pharmaceutical administration and food safety administration should work in close cooperation and promote proper enforcement.

(2) Guidance should be provided to manufacturers to help them perform quality control of their

products sufficiently and systems should be established under which the manufacturers engage in voluntary monitoring to prevent defective products. On-site inspection should be conducted on manufacturing sites and test results and other records regarding quality control should be checked.

(3) It is important to conduct random sampling tests in a planned manner in order to ensure proper labeling.

(4) If a label fails to contain information specified by the Cabinet Office Order or contains false information, or if it is found, as a result of progress in scientific findings, that it is inappropriate to make a claim of the special dietary use for the food covered by the permission, the permission may be rescinded pursuant to the provisions of Article 28 of the Act (including as applied *mutatis mutandis* pursuant to Article 29, paragraph (2) of the Act). Therefore, any such food that falls under these cases should be reported to the Food Labeling Division.

(5) In order to ensure the appropriate operation of the system, efforts should be made to monitor whether any food labeled as suitable for a special use is sold without labeling permission or approval. When such food is found, appropriate measures should be taken, such as giving instruction that permission or approval is required for labeling.

(6) From the perspective of facilitating nutrition management with the use of foods for special dietary uses, general advertisement by companies may fulfill a certain role in enhancing the visibility of such foods and securing their distribution as necessary. However, guidance should be provided to ensure that the advertisement remains within the range of the permitted or approved label and does not contain false or misleading information.

(7) If food not permitted as approved as FOSDU is advertised by claiming suitability for a special use, it could mislead consumers to believe that it is FOSDU. To prevent such inappropriate circumstances, appropriate measures should be taken with regard to companies that place such advertisements, such as instructing them to suspend the advertisement until they obtain permission or approval.

#### 11. Appropriate provision of information to targeted consumers

Foods for special dietary uses are products that the targeted consumers choose and buy themselves. Accordingly, it is desirable that the targeted consumers acquire basic knowledge on nutrition management and that professionals at medical institutions provide them with appropriate nutrition guidance.

Attached Form 1

Application Form for Labeling Permission for Foods for Special Dietary Uses

(DD/MM/YY)

To Commissioner of the Consumer Affairs Agency

Applicant's address

(in the case of a corporate body, location of its principal office)

Applicant's name: [Seal]

(in the case of a corporate body, its name and the name of its representative)

I hereby apply for permission for labeling for Foods for Special Dietary Uses pursuant to the provisions of Article 26, paragraph (1) of the Health Promotion Act (No. 103 of 2002) as follows.

Details

- (1) Name, address and date of birth of the applicant (if the applicant is a corporate body, its name, location of its principal office, and name of its representative)
- (2) Name and location of the business office (provide the name and location of the manufacturing site)
- (3) Product name
- (4) Expiration date or best before date
- (5) Ratio of combination of raw materials
- (6) Manufacturing method
- (7) Reason for seeking permission
- (8) Details of the label for which permission is sought
- (9) Amounts of nutritional composition and energy
- (10) Precautions for the method of intake, cooking, or storage if special attention is necessary
- (11) Labeling method

(Note)

1. This format should be Japanese Industrial Standard (JIS) A4 size.
- 2 Use ink for writing and write in clear block letters.

Attached Form 2

Application Form for Labeling Approval for Foods for Special Dietary Uses

(DD/MM/YY)

To Commissioner of the Consumer Affairs Agency

Applicant's address

(in the case of a corporate body, location of its principal office)

Applicant's name: [Seal]

(in the case of a corporate body, its name and the name of its representative)

I hereby apply for approval for labeling for Foods for Special Dietary Uses pursuant to the provisions of Article 29, paragraph (1) of the Health Promotion Act (No. 103 of 2002) as follows.

Details

- (1) Name, address and date of birth of the applicant (if the applicant is a corporate body, its name, location of its principal office, and name of its representative)
- (2) Name and location of the business office (provide the name and location of the manufacturing site)
- (3) Product name
- (4) Expiration date or best before date
- (5) Ratio of combination of raw materials
- (6) Manufacturing method
- (7) Reason for seeking approval
- (8) Details of the label for which approval is sought
- (9) Amounts of nutritional composition and energy
- (10) Precautions for the method of intake, cooking, or storage if special attention is necessary
- (11) Labeling method

(Note)

1. This format should be Japanese Industrial Standard (JIS) A4 size.
- 2 Use ink for writing and write in clear block letters.

Attached Form 3

(DD/MM/YY)

To Commissioner of the Consumer Affairs Agency

Prefectural Governor

Application for Labeling Permission for Foods for Special Dietary Uses

I hereby inform you that an application has been made as follows regarding the subject indicated above pursuant to the provisions of Article 26, paragraph (1) of the Health Promotion Act (No. 103 of 2002) and forward this application to you, upon finding no deficiency and confirming that the documents submitted are complete.

Details

1. Applicant's name
2. Product name

(Note)

1. This format should be Japanese Industrial Standard (JIS) A4 size.
- 2 Use ink for writing and write in clear block letters.

Attached Form 4

Shou-Shoku-Hyou No.

Labeling Permit for Foods for Special Dietary Uses

Applicant:

With regard to " " for which an application was made on (DD/MM/YY), I hereby permit the labeling for Foods for Special Dietary Uses as follows pursuant to the provisions of Article 26, paragraph (1) of the Health Promotion Act (No. 103 of 2002).

(DD/MM/YY)

Commissioner of the Consumer Affairs Agency

Details

Permit Number:

Content of labeling:

Other

Attached Form 5

Shou-Shoku-Hyou No.

Labeling Approval for Foods for Special Dietary Uses

Applicant:

With regard to " " for which an application was made on (DD/MM/YY), I hereby approve the labeling for Foods for Special Dietary Uses as follows pursuant to the provisions of Article 29, paragraph (1) of the Health Promotion Act (No. 103 of 2002).

(DD/MM/YY)

Commissioner of the Consumer Affairs Agency

Details

Approval Number:

Content of labeling:

Other

Attached Form 6

Notification of Changes in Information for Labeling for Foods for Special Dietary Uses

(DD/MM/YY)

To Vice-Commissioner of the Consumer Affairs Agency

Notifier's address

(in the case of a corporate body, location of its principal office)

Notifier's name: [Seal]

(in the case of a corporate body, its name and the name of its representative)

I hereby notify you of the following changes in the information for labeling for Foods for Special Dietary Use.

Details

1. Product name
2. Applicant
3. Date of labeling permission (approval)

Permit (Approval) Number:

4. Changes in information for labeling (Indicate by comparing the information before and after the changes)

(Note)

1. This format should be Japanese Industrial Standard (JIS) A4 size.
- 2 Use ink for writing and write in clear block letters.
3. Attach reference documents stating the reasons for the changes.

Attached Form 7

Notification of Invalidity of Labeling Permission (Approval) for Foods for Special Dietary Uses

(DD/MM/YY)

To Vice-Commissioner of the Consumer Affairs Agency

Notifier's address

(in the case of a corporate body, location of its principal office)

Notifier's name: [Seal]

(in the case of a corporate body, its name and the name of its representative)

I hereby notify you that the labeling permission (approval) for Foods for Special Dietary Uses falls under the following grounds for invalidity.

Details

1. Product name
2. Applicant
3. Date of labeling permission (approval)  
Permit (Approval) Number:
4. Grounds for invalidity of the labeling permission (approval)

(Note)

1. This format should be Japanese Industrial Standard (JIS) A4 size.
- 2 Use ink for writing and write in clear block letters.
3. Attach the permit or approval.

Reference Form 1

Request for Replacement of Application Form for Labeling Permission  
for Foods for Special Dietary Uses

(DD/MM/YY)

To Commissioner of the Consumer Affairs Agency

Applicant's address

(in the case of a corporate body, location of its principal office)

Applicant's name: [Seal]

(in the case of a corporate body, its name and the name of its  
representative)

I hereby request replacement of the application form for labeling permission for Foods for Special Dietary Uses submitted with regard to " " on (DD/MM/YY), to reflect the following changes.

Details

1. Changes

2. Grounds for changes

Reference Form 2

Request for Withdrawal of Application for Labeling Permission for Foods for Special Dietary Uses

(DD/MM/YY)

To Vice-Commissioner of the Consumer Affairs Agency

Applicant's address

(in the case of a corporate body, location of its principal office)

Applicant's name: [Seal]

(in the case of a corporate body, its name and the name of its representative)

I hereby withdraw the following application for labeling permission for Foods for Special Dietary Uses made pursuant to the provisions of the Health Promotion Act.

Details

1. Product name

2. Date of application

(DD/MM/YY)

Quality Control Report for Foods for Special Dietary Uses

(DD/MM/YY)

To Vice-Commissioner of the Consumer Affairs Agency

Reporter's address

(in the case of a corporate body, location of its principal office)

Reporter's name: [Seal]

(in the case of a corporate body, its name and the name of its representative)

I hereby report the status of quality control and other particulars as follows with regard to the Foods for Special Dietary Uses.

Permission No.	Product name	Food group of the food covered by the permission	Category of permission	Note
No. 12345	XX Jelly	Food products for people with dysphagia	Permission Criteria I	
No. 54321	YY Drink (strawberry flavor)	Comprehensive nutrition food products	—	See the attachment for the conversion in 100 kcal.