



The Society for Clinical Nutrition and Metabolism

APPLICATION FOR PRODUCTS TO BE APPROVED FOR INCLUSION IN IAPEN - DIRECTORY OF CLINICAL NUTRITION PRODUCTS AND SUPPLEMENTS

First Name: _____ Last Name: _____
Designation: _____ Gender: _____
Job Title: _____
Company Name: _____
Number / Street: _____
Town: _____ City: _____
Country: _____ Postal Code: _____
Tel No.: _____ Mob No.: _____
Email ID: _____

Address for Communication with Pin Code:

Product Name: _____

Product Category (Refer Annexure - 1 in Guidelines):

- Category 1: Infant Nutrition Products
- Category 2: Enteral Nutrition Product
- Category 3: Parenteral Nutrition Products
- Category 4: Supplements
- Category 5: Other products and equipments which are not suitable in above categories

Type of Submission: Type 1 Type 2 Type 3 Type 4
Refer Page 1 and 2 (Guidelines)

Product has been notified to

- FOOD AND SAFETY AUTHORITIES OF INDIA
- CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
- SIMILAR GOVERNMENT ORGANIZATIONS IN INDIA ONLY

If Yes, Mention the list of organizations Capital Letters (Attach separate sheet, if required)

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Information Check List:

Formulation Information about Product Available (Yes/No):

- | | | |
|--|------------------------------|-----------------------------|
| 1. Ingredients and Nutritional Information | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Nutritional Composition | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Nutritional Composition | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Manufacturing Process and Quality Control Mechanisms

- | | | |
|--|------------------------------|-----------------------------|
| 1. External Agency Certification Available | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Special instructions

- | | | |
|--|------------------------------|-----------------------------|
| 1. Special Instructions Required for the Product | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Standard Recipes Available | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Shelf Life

- | | | |
|--|------------------------------|-----------------------------|
| 1. Information about Shelf Life of Product Available | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Nutritionally Complete

- | | | |
|--|------------------------------|-----------------------------|
| 1. Product is "Nutritionally Complete" | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

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Information Check List:

- | | | |
|--|------------------------------|-----------------------------|
| 2. Ingredients Listing Follows Common Names | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Modification Required for different age group | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. For using, dietitian is required | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Evidence of Clinical Efficacy

- | | | |
|---|------------------------------|-----------------------------|
| 1. Clinical Trails Data Available | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Publication in Journal Available | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Evidence of Health Economic Benifits present | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. Similar type products were compared during study | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 5. Within India the original product is modified | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Attach separate document with details | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

If yes, write information about the modifications of product and clinical trails

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Information Check List:

6. If Equipment, Design and Drawing Available Yes No
 Attach separate document with details Yes No

Administration to the Patient

1. Administration information available Yes No
 Attach separate document with details Yes No
2. Methods and routes Info available Yes No
 Attach separate document with details Yes No
3. Reconstitution of the product before administration Yes No
 Attach separate document with details Yes No
4. If equipment, photo or video of procedure available Yes No
 Attach separate document with details Yes No

Contra - Indications And Precautions

1. Contra indication information available Yes No
 Attach separate document with details Yes No
2. Precautions available Yes No
 Attach separate document with details Yes No

Presentation

1. Information about form of product available Yes No
 Attach separate document with details Yes No
2. Additional givings were present along with product Yes No
 Attach separate document with details Yes No

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Information Check List:

Labelling, Packaging & Samples

1. Details about labelling available Yes No
Attach separate document with details Yes No
2. We agree to send sample to the below address Yes No
R R Siva Kiran
Joint Secretary, The Society for Clinical Nutrition and Metabolism,
Komatiapalli Post, Bobbili Mandal, Vizianagaram (Dt), Andhra Pradesh (St)
Pin: 535558; Mob: 0091 9986795754

Descriptive literature

1. Statement of how the product is promoted available Yes No
Attach separate document with details Yes No
2. Any Medical Claims during product promotion are present Yes No
Attach separate document with details Yes No
3. Articles in peer reviewer journal are present Yes No
Attach separate document with details Yes No

Promotional Policy Statement

- Yes No
Attach separate document with details Yes No

Market Availability

Information about product availability

Price of product to IAPEN Members: _____



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Information Check List:

The product comes under the purview of Infant laws in India (Brest feeding promotional network of India).

Yes No

I certify that all the information provided in the application form is true and accurate to the best of my knowledge and belief. The information submitted can be freely shared to the interested IAPEN Members ONLY and can be uploaded into the Members Area of IAPEN Website.

Name, Designation and Signature with Date

Name, Designation and Signature with Date

Name, Designation and Signature with Date