

APPLICATION FORM FOR PRODUCT REGISTRATION

A- DETAILS OF APPLICANT AND MANUFACTURER :

1- Applicant's :

- Name :Luxe Cluster.....

- Address :18/F, Canada Bank, Tower No. 315, Ang Doung St, Phnom Penh, 12202, Cambodia.....

- Phone :+855953 854.....

- Fax :
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- E-mail :sam@luxeccluster.com.....

2- Manufacturer's* :

- Name :MRO MaryRuth, LLC.....

- Address :1171 S Robertson Blvd, #148, Los Angeles, CA, 90035, USA.....

- Phone :630 703 8424.....

- Fax :n/a.....

- E-mail :ttaylor@maryruthorganics.com.....

* = Manufacturer responsible for final batch release .

Other manufacturers :

Name & address	Role**
Robinson Pharma, Inc.	manufactures finished product

** = e.g. "prepares semi-finished product", "packaging", "granulation", "manufactures bulk finished dosage form", "contract research organization", etc.

B- DETAILS OF PRODUCT :

1- Product Name :

- Commercial name :Biotin Gummies (Goji Berry, 60ct).....

- INN or Generic Name :n/a.....

- Dosage form and Strength : n/a

2- Product Description :

3- Qualitative & Quantity formula :

Active ingredient : Folate (as Calcium L-5-Methyltetrahydrofolate), Vitamin B12 (as Methylcobalamin), Biotin (as D-Biotin), Zinc (as Zinc, Fo-Ti (Polygonum multiflorum) Root Extract (12:1)

Other ingredients : Organic Isomato-oligosaccharides, Soluble Tapioca Fiber, Purified Water, Organic Erythritol, Pectin, Citric Acid, Organic Fruit Powder Blend (Strawberry, Blueberry, Raspberry, Tart Cherry, Pomegranate, Cranberry), Natural Flavor, Sodium Citrate, Vegetable Juice Color, Organic Rebaudioside A

C- REQUESTED PHARMACEUTICAL CATEGORY :

- Prescription : ☐

- Without prescription : ☒

D- INDICATION , POSOLOGY AND ROUTE OF ADMINISTRATION :

- Requested indication : n/a

- Recommended posology : n/a

- Recommended route of administration: n/a

E- ATTACHED INFORMATION :

- GMP Certificate ☒

- Certificate of a Pharmaceutical Product ☐

- Registration Certificate in other countries (if available) ☐

- Summary of product characteristics ☐

- Technical documents :

1- Quality ☒

2- Safety ☒

3- Efficacy ☐

- Samples :

2 Commercial boxes for registration purpose. ☒

- Registration fee ☒

F- PACKING SIZE :

- **Commercial packing** :
.....225cc HDPE bottle.....
- **Hospital packing**
.....n/a.....

G- SHELF LIFE :

.....24 months.....

Date :

Title :

Name :

Signature :