



Republic of the Philippines
Department of Health
Food And Drug Administration
Civic Drive, Filinvest City, Alabang, Muntinlupa City



FDA Registration No.: FR-4000009361391

CERTIFICATE OF PRODUCT REGISTRATION
(High Risk Food Product)

Pursuant to the provisions of Republic Act No.3720, otherwise known as the Food, Drugs and Devices, and Cosmetic Act, as amended by Executive Order No. 175, and Republic Act No. 9711, otherwise known as the Food and Drug Administration Act of 2009, and other applicable laws, rules and regulations, the registration of the High Risk Food Product described hereunder is granted approval.

Brand Name: FERALAC
Product Name: MALUNGGAY 500 mg FOOD SUPPLEMENT CAPSULE (Registered as Food Supplement WITH NO APPROVED THERAPEUTIC CLAIMS)
Packaging: CLEAR POLYVINYL CHLORIDE (PVC) FILM OF 0.25 MM THICK AND MATTE FINISHED ALUMINUM FOIL OF 0.02 MM THICKNESS
Company Name and Address: JOHNTANN INTERNATIONALE PHARMACEUTICAL CORP., 25 KABIGNAYAN ST., TATALON, QUEZON CITY, METRO MANILA
LTO No.: LTO-3000004027358
Manufacturer Name and Address: SAN MARINO LABORATORIES CORPORATION, 1 CRISANTO DELOS REYES ST., JAVALERA, GEN. TRIAS, CAVITE

The company hereby ensures that they shall respond and cooperate fully with the FDA with regard to any subsequent post-marketing activity initiated by the FDA. Further, the company shall be responsible for ensuring that each batch/lot of the product continues to meet all the legal requirements, and conforms to all the standards and specification of the product declared to the FDA, including compliance to the list of obligations enumerated at the reverse side of this document.

The authorization is subject to suspension, cancellation, or recall should any violation of FDA laws, and its implementing rules and regulations, involving the product be committed.

Issued on **19 May 2022** and valid until **20 April 2027** .

BY AUTHORITY OF THE DIRECTOR GENERAL


PILAR MARILYN M. PAGAYUNAN
Director IV, Center for Food Regulation and Research



DECLARATION

I undertake to respond to and cooperate fully with Food and Drug Administration (hereafter referred to as "THE AUTHORITY") with regard to any subsequent post-marketing activity initiated by the authority.

I undertake to ensure that the product's technical and safety information is made readily available to the authority concerned and to keep records of the distribution of the products for product recall purposes, and other purposes as provided in existing laws, rules and regulations.

I undertake to notify the Authority of any adverse event, fatal or life threatening serious adverse event as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 48 hours after first knowledge.

I undertake to act immediately on potential food safety concerns should my product source or origin declare/announce/notify a product recall order or any actions taken involving safety issues, and I am responsible to stop distribution or remove product from the outlets or take appropriate actions and inform the Authority on risk management actions undertaken and/or to be undertaken.

I declare that the particulars given in this product registration are true, all data, and information of relevance in relation to the registration have been supplied and that the documents enclosed are authentic or true copies.

I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.

I understand that I cannot place reliance on the acceptance of my product registration by the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

I understand that I will need to comply with all the labeling requirements as stipulated by Administrative Order No. 2014-0030 and other pertinent laws and regulations associated with labeling.

I undertake to declare truthful product information and shall not cause the dissemination of any false, deceptive or misleading advertisement by print, radio, television, outdoor advertisement or other medium for the purpose of inducing or which is likely to induce directly or indirectly the purchase of the product.

I understand that any change or variation in the formulation of registered product will require new registration to the Authority and the subject shall be treated as new product.

I hereby agree and affirm full responsibility for the safety of my product/s and agree to indemnify and/or hold FDA free and harmless against any issues that may arise in the manufacture, import, export, distribute, transfer, promote, advertise, sponsor, sell, offer for sale, and where appropriate the use and testing, and marketing of my food product/s

I hereby understand that the registration of the product herein granted shall not be interpreted or construed as an endorsement or representation by FDA that I have the right or privilege to the use of the name or brand so registered. I hereby agree and affirm to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or intellectual property rights from the registration of the product listed on the first page thereof.

REMARKS:

Declare the prescribed format of nutrition information (delete "Malunggay Powder" from the table), expiration date in prescribed format and updated FR number on the label.