

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

FDA Registration No.: FR-4000001088629

CERTIFICATE OF PRODUCT REGISTRATION

(Medium 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 Medium Risk Food Product described hereunder is granted approval.

Product Name: CALCIUM CARBONATE (1250 MG) + VITAMIN D3 (250 IU)

FOOD SUPPLEMENT TABLET (Registered as Food

Supplement with NO APPROVED THERAPEUTIC CLAIMS)

Brand Name: OSCIVIT

Packaging: ALU-PVC; BLISTER PACK

Company Name: ALMAN PHARMACEUTICALS INC.

Company Address: U-1 PATRICIA BLDG, EDSA MAGALLANES, MAKATI

CITY

Company LTO: CFRR-NCR-FW-1812

Manufacturer Name
and Address:

LIFESQUARE LABORATORIES INC., BLK 2, LOT 10-11
MOUNTVIEW INDUSTRIAL PARK II, BRGY. BANCAL

CARMONA 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 22 February 2017 and valid until 22 February 2022.

BY AUTHORITY OF THE DIRECTOR GENERAL

PILAR MARILYN M. PAGAYUNAN

Director IV, Center for Food Regulation and Research

Remarks: On the label: a) Declare Nutrition Facts and expiration date in prescribed format in accordance to AO 2014-0030. b) Indicate the precaution "For Adults use only. Not intended for Children, Pregnant and Lactating Women." c) Declare the function of the food additives.



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. 2014-030 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

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MERCHANT / AGENCY DEPOSIT ACCOUNT NUMBER 0 3 9 2 2 2 2 0 2 2 Reference Number 1 LIPE SQUARE LABORATORIES, INC.		MERCHANT / AGENCY NAME FOA FOOD CLEARING ACCOUNT Printed Name and Signator Separation Legislator / Representative BARD LOWE CLEAR C		
Reference Number 3 (Numeric) RENEWAL OF CPR (FOOD) OGAVIT TABLET Amount	FDA FOOD Cling. Acct. APPLICATION NAME OF APP/	10:55 frxn. Sed. OASH No. 039 NO. 4000		TATANCE INTO A LAT
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