



20 APR 2022

FDA ADVISORY

No. 2022-0943-A

PARA : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

PAKSA : Babala sa Publiko Tungkol sa Pagbili at Paggamit ng mga Sumusunod na Hindi Rehistradong Gamot:

1. **21st Century Extra Strength Hair, Skin & Nails With Antioxidants A, C & E, B-Complex Vitamins & Minerals 90 Tablets**
2. **CHINTA Paracetamol 100 Tablets**
3. **KIRKLAND Signature One Per Day Super B-Complex with Electrolytes 500 Tablets**

Pinapayuhan ng Food and Drug Administration (FDA) ang publiko laban sa pagbili at paggamit ng mga sumusunod na hindi rehistradong gamot:

21st CENTURY. healthy renewal formula™
EXTRA STRENGTH
Hair, Skin & Nails
With Antioxidants A, C & E, B-Complex Vitamins & Minerals
5000 mcg of Biotin PER SERVING
90 TABLETS | DIETARY SUPPLEMENT

Supplement Facts
Serving Size: 3 Tablets
Amount Per Serving: 9000 mcg Biotin (180,000% DV)
Vitamin C (Ascorbic Acid) 50 mg (100% DV)
Vitamin E (D-Alpha-Tocopherol) 10 mg (200% DV)
Vitamin B-1 (Thiamin) 2 mg (40% DV)
Vitamin B-2 (Riboflavin) 2 mg (40% DV)
Vitamin B-3 (Nicotinamide) 20 mg (400% DV)
Vitamin B-5 (Pantoic Acid) 10 mg (200% DV)
Vitamin B-6 (Pyridoxine HCl) 2 mg (40% DV)
Vitamin B-12 (Cyanocobalamin) 250 mcg (5000% DV)
Vitamin B-7 (Biotin) 5000 mcg (100,000% DV)
Vitamin B-9 (Folate) 100 mcg (200% DV)
Vitamin B-10 (Decalamin) 10 mg (200% DV)
Vitamin B-11 (Methylcobalamin) 1000 mcg (20,000% DV)
Vitamin B-12 (Cyanocobalamin) 250 mcg (5000% DV)
Vitamin B-13 (Inositol) 100 mg (200% DV)
Vitamin B-14 (Choline) 100 mg (200% DV)
Vitamin B-15 (Pantoic Acid) 10 mg (200% DV)
Vitamin B-16 (Choline) 100 mg (200% DV)
Vitamin B-17 (Silymarin) 100 mg (200% DV)
Vitamin B-18 (Choline) 100 mg (200% DV)
Vitamin B-19 (Choline) 100 mg (200% DV)
Vitamin B-20 (Choline) 100 mg (200% DV)
Vitamin B-21 (Choline) 100 mg (200% DV)
Vitamin B-22 (Choline) 100 mg (200% DV)
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Vitamin B-95 (Choline) 100 mg (200% DV)
Vitamin B-96 (Choline) 100 mg (200% DV)
Vitamin B-97 (Choline) 100 mg (200% DV)
Vitamin B-98 (Choline) 100 mg (200% DV)
Vitamin B-99 (Choline) 100 mg (200% DV)
Vitamin B-100 (Choline) 100 mg (200% DV)

21st CENTURY. healthy renewal formula™
EXTRA STRENGTH
Hair, Skin & Nails
Antioxidants A, C & E
Plus B-Complex Vitamins & Minerals
5000 mcg of Biotin PER SERVING
90 TABLETS | DIETARY SUPPLEMENT

21st CENTURY. healthy renewal formula™
EXTRA STRENGTH
Hair, Skin & Nails
DISCOVER BEAUTIFUL SUPPORT
21st Century's healthy renewal formula™ Extra Strength Hair, Skin & Nails works to help support your natural beauty from within. Biotin and vitamins A and E help promote Biotin, hair, strong nails and vibrant skin.
Biotin is important for the maintenance of healthy skin and hair and supports nail growth.
Vitamin A promotes a healthy cellular environment for healthy skin and overall health.
Vitamin C is an antioxidant that slows the rate of free radical damage to the body.
Vitamin E helps keep cell blood cells.
Use Hair, Skin & Nails to Support:
• Skin Moisture Level*
• The Fullness of Hair*
• Nail Strength & Health*
*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.

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EXTRA STRENGTH
Hair, Skin & Nails
Antioxidants A, C & E
Plus B-Complex Vitamins & Minerals
5000 mcg of Biotin PER SERVING
90 TABLETS | DIETARY SUPPLEMENT
ACTUAL SIZE

21st Century Extra Strength Hair, Skin & Nails With Antioxidants A, C & E, B-Complex Vitamins & Minerals 90 Tablets
Manufactured by: 21st Century Healthcare Inc. - 2119 S. Wilson St., Tempe, AZ 85285 USA

Larawan 1. Hindi rehistradong gamot





CHINTA Paracetamol 100 Tablets

Manufactured & Distributed by: Chinta Trading Co., Ltd. - 420 Soi Suthiporn 2, Asoke-Dindaeng, Bangkok, Thailand

Distributed by: Chin Hong & Co., Hong Kong

Larawan 2. Hindi rehistradong gamot



KIRKLAND Signature One per Day Super B-Complex with Electrolytes 500 Tablets
 Manufactured by: Costco Wholesale Corporation - P.O. Box 34535, Seattle, WA 98124-1535 USA

Larawan 3. Hindi rehistradong gamot

Napatunayan sa pamamagitan ng isinagawang *Post-Marketing Surveillance* (PMS) ng FDA na ang mga nasabing gamot ay hindi dumaaan sa proseso ng rehistrasyon ng Ahensya at hindi nabigyan ng kaukulang awtorisasyon tulad ng *Certificate of Product Registration* (CPR). Dahil dito, hindi masisiguro ng Ahensya ang kalidad, kaligtasan at bisa nito. Samakatuwid, ang paggamit ng nasabing mga ilegal na produkto ay maaaring magdulot ng panganib sa kalusugan.

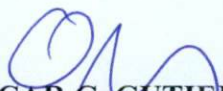
Alinsunod sa *Republic Act No. 9711*, o ang *Food and Drug Administration Act of 2009*, ang paggawa, pag-angkat, pagbenta, pamamahagi, paglipat, promosyon, pagpapatalastas o *sponsorship* ng produktong pangkalusugan nang walang kaukulang awtorisasyon mula sa FDA ay ipinagbabawal.

Ang lahat ng establisyamento at/o entidad ay binabalaang huwag mamahagi ng nasabing mga ilegal na produkto hanggang sa ito ay mabigyan ng kaukulang awtorisasyon. Karampatang parusa ay mahigpit na ipatutupad sa mga lalabag. Ugaliing tignan kung rehistrado ang produkto sa FDA sa pamamagitan ng *FDA Verification Portal feature* na makikita sa <https://verification.fda.gov.ph>.

Hinihiling sa lahat ng *Local Government Units* (LGUs) at *Law Enforcement Agencies* (LEAs) na tiyaking ang mga produktong ito ay hindi maibebenta o magagamit sa kanilang mga nasasakupan.

Para sa karagdagang impormasyon at katanungan, maaaring mag-email sa info@fda.gov.ph. Upang mag-report ng patuloy na pagtitinda o pangangalakal ng mga hindi rehistradong gamot, mag-email sa ereport@fda.gov.ph. Maaari ring tumawag sa *Center for Drug Regulation and Research* (CDRR) sa numerong (02) 8809-5596. Para sa mga hinihinalang hindi kanais-nais na reaksyon sa gamot, i-report agad sa FDA gamit ang *link* na ito: <https://primary-reporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> at kumpletuhin ang mga kinakailangang impormasyon.

Ang lahat ay hinihikayat na palaganapin ang mga nakasaad na impormasyon.


DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN:



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