

Governor
John R. Kasich

Lieutenant Governor
Mary Taylor

ODA Director
David T. Daniels

ODH Interim Director
Lance D. Himes

DATE: April 25, 2014

TO: Health Commissioners, Directors of Environment Health and Interested Parties

RE: Recall Announcement (ODA/ODH) 2014-050

Nano Well-being Health Inc. Issues Voluntary Nationwide Recall of Super Arthgold Due to Undeclared Ingredients

April 21, 2014 - La Mirada, CA, Nano Well-being Health Inc. is voluntarily recalling lot L1P1-6100/Expiration date June 25, 2016 and lot L1P2-6000/Expiration date September 16, 2016 of Super Arthgold, 500 mg capsules to the consumer level. FDA laboratory analysis has found the product to contain chlorzoxazone, diclofenac and indomethacin, making it an unapproved new drug. To date, no illness or injuries have been reported.

The product is used as a dietary supplement for joint pain and arthritis and is packaged in bottles of 120 capsules. The product was distributed nationwide to wholesalers.

Use of this product containing the undeclared drug ingredients listed above, has a reasonable probability of resulting in fatal adverse events in consumers and patients with underlying illnesses, including known allergy to the hidden ingredients, cardiac, gastrointestinal, hepatic, and renal conditions as well as patients who recently undergone cardiac bypass graft surgery. Consumers would be unaware that the product contains Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (and other ingredients), may inadvertently overdose by taking another NSAID concurrently, thus increasing the risk for NSAID associated adverse events, which include but are not limited to, myocardial infarction, stroke, congestive heart failure, renal toxicity, and bleeding, ulceration, or perforation of the stomach or intestines.

Nano Well-being Health Inc. is notifying its distributors and customers by letter and phone call and is arranging for replacement of all recalled products. Consumers/distributors/retailers that have product which is being recalled should stop using and return to place of purchase.

Consumers with questions regarding this recall can contact Nano Well-being Health Inc. by phone at 1-714-515-4600 or e-mail address of at nanowellbeingh@gmail.com, Monday to Friday from 9:00 AM to 5 PM, Pacific Standard Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Complete and submit the report Online: <http://www.fda.gov/MedWatch/report.htm>
Regular Mail or Fax: Download form <http://www.fda.gov/MedWatch/getforms.htm> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.