Main Products, Inc. Issues Voluntary Nationwide Recall of Umary Acido Hialuronico, Suplemento Alimenticio Due to the Presence of Undeclared Drug Ingredients: Diclofenac and Omeprazole

Company Contact: Nelson Pont Company Name: Main Products, Inc., 1551 Glenwood Springs Ave., Chula Vista CA, 91913 Phone: 619-870-7301

**FOR IMMEDIATE RELEASE** – 07/22/2024 – Chula Vista, CA – Main Products, Inc. is voluntarily recalling all lots of "Umary Acido Hialuronico, Suplemento Alimenticio – 30 Capletas de 850mg" to the consumer level. FDA laboratory analysis confirmed that UMARY has been found to be tainted with the drug ingredients, diclofenac and omeprazole. Products containing diclofenac and omeprazole cannot be marketed as dietary supplements. Umary is an unapproved new drug for which safety and efficacy have not been established and, therefore, subject to recall.

Risk Statement: Diclofenac is a non-steroidal anti-inflammatory drug (commonly referred to as NSAIDs). There is a reasonable probability that consumption of high levels of undeclared diclofenac could result in serious adverse events that include cardiovascular, gastrointestinal, renal, and anaphylaxis in patients taking concomitant NSAIDs and/or anticoagulants, such as Warfarin, in those who have allergies to diclofenac, or those with underlying cardiovascular, gastrointestinal, renal, and hepatic illnesses.

Omeprazole is a proton pump inhibitor (commonly referred to as PPI) used to treat gastric (stomach) acid-related disorders. PPI medicines may cause serious skin reactions, abdominal pain, diarrhea, nausea, and headache. This hidden ingredient may mask stomach issues such as erosions, ulcers, and stomach cancer, and it can also interact with other medications and should not be taken with certain medications.

The product is used as a dietary supplement promoted and sold for pain and is packaged in bottles with 30 caplets. The affected product includes all lots within expiry. The product was distributed via online store Main Products, Inc. on Amazon.com.

Main Products, Inc. is notifying its customers by email and is arranging for the return of all recalled products. Consumers that have Umary which is being recalled should stop using and return to place of purchase. Consumers may return the products to the address below via mail:

## Main Products, Inc., 1551 Glenwood Springs Ave., Chula Vista CA, 91913

Consumers with questions regarding this recall can contact Main Products, Inc. at <a href="mainproductsumaryrecall@gmail.com">mainproductsumaryrecall@gmail.com</a> by e-mail 24 hours a day and can expect a 24 to 48-hour

response time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

A notice will be posted on Main Products, Inc.'s website at <a href="https://www.main-products.com">www.main-products.com</a>

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
- Regular Mail or Fax: <u>Download form</u> 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.







