Statement for Customers – NYAG Investigation Letter

On February 23, 2015, Nature's Way received a letter which constituted "a request for documents and information relating to an ongoing investigation by the New York State Office of the Attorney General ("NYAG") concerning the authenticity and purity of herbal dietary supplements and associated marketing." The letter indicates that the "NYAG is reviewing the sufficiency of the measures manufacturers and retailers are taking to independently assess the validity of their representations and advertising in connection with the sale of herbal supplements."

To be clear, the letter from the NYAG makes no allegations against Nature's Way and provides no indications of any quality or compliance problem with any Nature's Way product. The letter is simply a "request" for documents and information. The letter does state that the "NYAG recently commissioned an analysis that used DNA barcoding technology to test several popular herbal dietary supplements sold at four retailers in New York State." These four retailers were Target, GNC, Wal-Mart and Walgreens. None of the products tested were Nature's Way products. The DNA test results reported by the NYAG were specifically in regards to the store brands carried by each of the four named retailers.

Dietary supplements are regulated by the federal Food and Drug Administration (FDA). The Dietary Supplement Health and Education Act of 1994 (DSHEA) authorized FDA to issue Good Manufacturing Practices (GMPs) regulations to cover all aspects of supplement manufacturing, and the FDA released those rules in 2007 (21 CFR Part 111). Among those requirements, manufacturers must conduct "at least one appropriate test or examination" to verify the identity of any ingredient, 21 CFR §111.75(a), and must also test their finished products to assure they meet the products' specifications for identity, purity, strength and composition, 21 CFR §111.75(c).

Nature's Way routinely conducts a variety of chemical analyses (e.g., liquid chromatography, mass spectrometry, etc.) to assure all products do in fact contain the appropriate ingredients, and records of these test results are kept to satisfy the requirements of the federal regulations. The FDA inspects Nature's Way for compliance with these federal requirements. The FDA does not require DNA barcode testing, and it recently reiterated that "We [FDA] currently use chemical markers or fingerprints for ingredient verification."

Nature's Way utilizes the expertise of qualified 3rd party laboratories and our own multi-million dollar state-of-the-art laboratory to appropriately test every batch of raw material and product for identity, purity, strength, composition and limits of specified contaminants as required in 21 CFR Part 111. The Nature's Way laboratory employs the use of advanced analytical equipment and highly trained chemists and microbiologists. Some of the testing on raw ingredients and finished product are summarized below.

Herbal Identity Procedures:

- **Macroscopy/Microscopy Tests** – using the naked eye/microscope to examine the development, form, and structure of plant material using authoritative herbal pharmacopeia
- **High Performance Thin Layer Chromatography (HPTLC) Identity Tests** – verifies the identity of botanical ingredients versus certified botanical reference materials
- **High Performance Liquid Chromatography (HPLC)** – identifies and quantitatively measures specific marker constituents in herbs

- **DNA Barcoding** – useful for testing herbs with viable DNA to confirm identity by comparing gene sequences from the sample to a certified botanical reference sample

Potency and Composition Quality Assurance Procedures:

- **Inductively Coupled Plasma Optical Emission Spectrometry** (**ICP-OES**) – tests for mineral presence and quantity to ensure raw material or finished product potency
- **High Performance Liquid Chromatography (HPLC)** –tests for various vitamin presence and quantity to ensure raw material or finished product potency
- **Disintegration, Dissolution** – ensures that the tablet or capsule dissolves in the body; performed according to standards specified by the United States Pharmacopoeia
- **Capillary Electrophoresis (CE)** – tests for the presence and quantity of amino-acid containing ingredients
- **Gas Chromatography – Mass Spectrometry (GC-MS)** – measures the quantity of volatile active ingredients
- **FTIR** – tests for unique "chemical fingerprints" to identify non-botanical ingredients
- **Stability Testing**- testing on finished product to ensure that potency of all labeled ingredients are met throughout labeled shelf life

Contaminant Testing Procedures:

- **Gas Chromatography – Mass Spectrometry (GC-MS)** –contaminants such as pesticides and residual solvents
- **Inductively Coupled Plasma Mass Spectrometry (ICP-MS)** – tests for trace heavy metal contaminants such as lead, mercury, arsenic and cadmium
- **Microbiological** – tests examine for bacterial, yeast, mold, and pathogen contamination

Routine third party verification is a critical element of our assurance of on-going compliance to 21 CFR Part 111. Nature's Way continues to hold Dietary Supplement GMP Certification through NSF International. NSF International is, an independent, not-for-profit organization that confirms compliance to Dietary Supplement GMP's (21 CFR 111) through regular onsite audits and inspections. For on-going certification, Nature's Way is audited by NSF International every six months in order to confirm facility compliance and renew cGMP certificate # 3W510-01.

Nature's Way holds a GMP Certificate from the Australian Department of Health's Therapeutic Goods Association (TGA). Dietary supplement products are regulated as "complementary medicines" in Australia; requiring manufacturers to go through a rigorous on-site inspection and verification of compliance to GMP before a certificate is awarded.

Nature's Way is a licensed site for the production of Natural Health Products (NHPs) marketed in Canada. The Canadian site licensing system requires that all manufacturers, packagers, labelers, and importers be licensed. Sites must have procedures in place for distribution records and product recalls and for the handling, storage and delivery of their products. They must also demonstrate that they meet good manufacturing practice requirements. Good Manufacturing Practices (GMPs) must be employed to ensure product safety and quality.

Nature's Way is also audited throughout the year by other regulatory and/certifying bodies including the, State of Wisconsin Department of Agriculture, STR-Registrar LLC, Orthodox Union (Kosher), IFANCA (Halal) and Quality Assurance International (QAI). QAI, a USDA-accredited certifying agent, confirms that "organic" and "made with organic" product formulations, as well as manufacturing facilities and processes, are compliant with the National Organic Program (NOP). Since receiving its organic certificate # 106450A in 2008, Nature's Way is audited on an annual basis to confirm compliance with the National Organic Program.

Nature's Way intends to cooperate with the NYAG request for documents and information, as we are proud of our Quality Assurance processes and the steps that we take to both comply with the law and produce products of the highest quality.