

February 25, 2009

To our valued customers,

Madre Labs™, Inc. has been many years in the making, but was not a formal entity until September, 2008. Due to such a long gestation period, the founders (with over 40 years combined experience in the dietary supplements industry) have been able to study the trends, developments and emerging science of how herbs, natural foods and nutraceuticals can support optimal well-being.

Quality and Efficacy is Our Mission:

To create truly innovative and unique formulations of the highest quality, assisting our health-minded customers in supporting their well-being, and offering finished products that we OURSELVES want to take.

All of us at Madre Labs™ are committed to following our founding mission and principles to guarantee the consistent quality of our premium, innovative products. How do we accomplish this?

1. Raw Material Sourcing

Our raw materials are selected exclusively on the basis of quality & efficacy (the science), and not on the basis of cost. As you may know, there are various grades and origins of nutraceutical raw materials. We have chosen the very best that is available, and generally speaking, the most expensive. Most of our qualified raw materials are either manufactured in the United States or imported from Japan & Europe. We rely on reputable industry suppliers and frequently use “Branded” ingredients. All of our qualified suppliers are required to perform rigorous analytical tests, including but not limited to the following analyses: Material Identification, Heavy Metals, Microbial, Pesticide Residue and Organic Volatile Impurities (OVI). We require Certificates of Analysis, Specification Sheets, Material Safety Data Sheets and testing results from the most sophisticated analytical methods (such as: HPLC, HPTLC, GC, UV-VIS, FTIR, NIR and ICP-MS) to ensure the highest quality finished products. We also conduct our own third party testing to confirm the results of our suppliers’ testing.

2. Contract Manufacturing

Madre Labs™ employs one of the Industry’s top Contract Manufacturers to produce our Premium, Innovative Formulations. Our Contract Manufacturer has successfully completed several quality audits, thus gaining recognition for meeting the highest standards of quality. This company has a Pharmaceutical Drug Manufacturing License from the California State Health Department (Food & Drug Branch), is cGMP Certified by the Natural Products Association (NPA), and also certified by the Australian Government’s TGA (Therapeutic Goods Administration). Our Contract Manufacturer is an official Pharmaceutical Drug Manufacturer that also manufactures Dietary Supplements to the same standards as pharmaceutical drugs.

a. Receipt of Incoming Materials

All raw materials, components, packaging, and labeling materials are received through the same controlled entrance into our contract-manufacturer’s facility, and are thoroughly checked, counted, and identified by trained personnel before being allowed into the Quarantine area.

b. Quarantine & Release

All raw materials, components, packaging, and labeling materials are held in the Quarantine area until sampled, tested, examined, and released for use by the Quality Control department. Sampling is performed according to written Standard Operating Procedures (SOPs) designed to prevent contamination of raw materials, components, and packaging materials. When the samples have been received, Quality Control personnel perform the specific test procedures, document the results and match them against all specifications. All raw materials, components, packaging, and labeling materials which pass inspection will receive a Release sticker. Only containers bearing this Release sticker are allowed out of Quarantine and into the main warehouse.

c. Weighing

The first step of the manufacturing process involves weighing the raw materials, precisely as indicated on the Master Batch Production Record. Each raw material is identified by its name and code number and weighed, using a calibrated scale. It is then placed into a clean, properly labeled container, indicating: raw material, weight, raw material lot number, product name, code, and lot number. A complete double-check is performed, to ensure that the information is correct and matches the requirements of the Master Batch Production Record. Upon completion of weighing all the raw materials for a production batch, all documentation is rechecked and signed off by qualified technicians before sending all materials to the Compounding/Blending department.

d. Compounding/Blending

It is critical to prevent all Contamination or Cross-Contamination of raw materials during processing, and especially during the Blending/Compounding Phase. Each processing room is fully equipped with an advanced air-flow system designed to minimize the chances of cross-contamination. Technicians identify each of the weighed raw materials and compare them to the requirements of the Master Batch Production Record. As each procedure is performed, the material compounder documents that the step has been completed and a second technician verifies and documents that fact. Also, as each raw material is added to the batch, the material compounder documents the addition and a second technician verifies and documents the addition. Once all compounding steps are complete, the uniform blend is discharged into poly-lined, "in-process", labeled containers. Samples are taken according to written SOPs. The Master Batch Production Record is reviewed and submitted to the Quality Control department along with the samples for "in-process" testing to assure that the proper specifications have been achieved.

e. Filling & Packaging

The Packaging department consists of two divisions: 1. Bottle filling (counting & filling of unit dose forms such as tablets, hard-shell capsules, and softgel capsules) 2. Powder filling (packaging of powder blends, such as drink mixes). Both areas are controlled by written SOPs, designed to assure the proper fill, components, and labeling for each packaging run. The Packaging Record provides all necessary specifications, and allows for full documentation of the packaging phase. The Packaging Record then becomes part of the Master Batch Production Record, which allows all processing and packaging information to be filed in the Document Control department. Packaging runs are monitored to ensure that the final product meets all specifications. At the end of the packaging run, the Packaging Record and finished samples are submitted to the Quality Control department for final analysis & testing prior to release for shipping.

f. Quality Control & Quality Assurance (Overview)

The Quality Control department performs all required tests and assays on raw materials, in-process goods, and finished products according to cGMP regulations. All test specifications, standards, sampling plans, procedures, and other laboratory control methods are continually reviewed and approved by the QC Dept. Independent third-party labs are regularly used to assure quality compliance. The Quality Assurance department cross-checks all stages of the manufacturing process for compliance with written Standard Operating Procedures. The QA group routinely conducts in-house audits to assure conformity to cGMP requirements and the effective operation of the total system. Lab procedures & methods and instrument calibration protocol are also monitored for accuracy, precision and reproducibility. Finished products are released, once the final inspection has been completed by the QA Dept. in accordance with written SOPs.

Like our Madre Labs™ Mission Statement implies – we want to assure you, our loyal customers, that you will receive the highest quality, premium nutraceutical formulations that we OURSELVES take.

Sincerely yours in Health,
Madre Labs™, Inc. Management