



nutrasource diagnostics inc.

Nutrition and Nutraceutical Research Division

2008



nutrasource diagnostics inc.

Corporate Headquarters
120 Research Lane, Suite 203
University of Guelph Research Park
Guelph, Ontario, Canada
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www.nutrasource.ca

WHY NUTRASOURCE?

The regulatory environment is becoming increasingly complex for the introduction of natural health products or supplements to the marketplace. Canada has taken on a leadership position in defining the framework required for licensing natural products, including: provisions on definitions, product licensing, site licensing, good manufacturing practices, clinical trials, labeling and packaging requirements, and adverse reaction reporting. It is anticipated that other country regulatory agencies will follow suit in a manner similar to the International Congress on Harmonization [ICH] process that occurred for regulated drugs. In fact, the FDA Centre for Food Safety and Applied Nutrition recently published a list of initiatives for 2004, which included publishing guidance on manufacturing practices, adverse event monitoring and substantiation of "efficacy" claims.

Nutrasource Diagnostics Inc. [NDI], located in the internationally recognized University of Guelph Research Park, is the world leader in human clinical trials, human diagnostics, product analytics, and regulatory consulting for the natural health product industry. NDI is ideally positioned to expedite the process of bringing new natural health products or supplements to the marketplace in a manner that will withstand the most rigorous scrutiny by regulatory agencies. Whether you require a partner to manage and perform the entire process or a partner to assist with one segment, you can take comfort in knowing that NDI will do what it takes to meet and exceed your expectations.

NDI has long standing expertise at all points along the complex path required to successfully launch a natural health product or supplement. When you have a product to get to market, we develop the solutions you require. Our experience, expertise, and services include regulatory submissions, preparation and packaging of clinical trial materials, clinical trial design, project management, data management, biostatistics, study reports, expert reviews from the literature and assistance with publication in respected journals.

NDI will assist your company on the path to commercialization within the Canadian marketplace. NDI's expertise will provide regulatory service and compliance in obtaining Health Canada market approval for your products.

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REGULATORY SERVICES

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- **Health Canada Consulting Services**
- **Clinical Literature Reviews and Journal Reference Searches**
- **Regulatory/Analytical Services**

➤ **HEALTH CANADA CONSULTING SERVICES:**

Allow NDI to offer regulatory assistance in preparation of any of the following items for the **Natural Health Products Directorate [NHPD]** or **Therapeutic Products Directorate [TPD]**:

- **Natural Product Number [NPN] Licence Applications**
 - Compendial Health Claims
 - Traditional Health Claims
 - Non-Traditional [Non-Compendial] Health Claims
 - Homeopathic Health Claims
- **NHPD or Drug Master Files**
 - Product formulations
 - Product manufacturing processes
 - Product delivery vehicles [packaging materials] ie/ capsules
- **NHPD Site Licences**
 - Manufacturers
 - Packagers
 - Private labelers
 - Importers
- **NHPD Cosmetic Applications**

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Allow NDI to:

- provide a regulatory strategy for product classification and submission to Health Canada, as well as expert advice and support to ensure your product will meet current Health Canada standards
- advise on quantities of medicinal ingredients in order to meet current Health Canada guidelines
- determine the eligibility of non-medicinal ingredients
- prepare efficacy summary reports and safety summary reports for each medicinal ingredient(s) in your product
- assist with health claim requirements for your product
- determine relevant risk information required for product labeling
- assist with French language translation for your product label
- provide supportive scientific information required for the registration of a combination product
- prepare and submit your product licence application to Health Canada
- act as a liaison with Health Canada until your product is approved for licensed sale in Canada

Project quotes are available on a case by case basis. To obtain an estimate, please contact NDI to receive a client questionnaire.

➤ **CLINICAL LITERATURE REVIEWS AND JOURNAL REFERENCE SEARCHES**

If you require clinical journal references as supporting documentation for your scientific project, or require a literature review for personal and/or professional interest, let NDI assist you! Each NDI clinical literature review is authored by a scientific researcher and is subject to external peer review by a resident expert in the field.

NDI has full access to millions of nutritional and medical titles, journals, books, reviews and electronic publications. Such access ensures that all clinical literature reviews and references offer an appropriate assessment of current scientific literature, and will be highly defensible when held up to scientific scrutiny.

Types of literature reviews:

- For the Consumer
- For the Health Science Industry
- For the Medical Professional / Health Care Practitioner

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➤ REGULATORY/ANALYTICAL SERVICES

If your company requires Quality Summary Report completion for a current or future Product License Application to Health Canada, Nutrasource Diagnostics Inc. has a full analysis suite solution to fulfill your regulatory obligations. Along with its world renowned International Fish Oil Standards Program, Nutrasource has developed a complete assay panel for your company to easily comply with Health Canada guidelines for Quality Summary Reports, to ensure your application processing time is kept to a minimum.

QUALITY SUMMARY REPORT TESTS INCLUDE:

Quantitative Testing

- Active ingredient, potency, etc.
- Nutritional Assessment - Label
- Nutritional Analysis
- EFA Analysis

Basic Analysis

- Disintegration
- Acid Value (Free Fatty Acids, Anisidine Value, Peroxide Value)
- Fill weight Variation and Average Fill Weight

Microbiological testing

- Total Aerobic Microbial Count
- Contaminating Fungus (Yeast and Molds)
- Escherichia coli*
- Staphylococcus aureus*
- Pseudomonas aeruginosa*
- Salmonella* spp.

Heavy Metals Testing

- Mercury
- Other Trace Metals (As, Cd, Cr IV, Pb, Ni)

Pesticides and Toxins

- PCBs, Dioxins and Furans
- OC Pesticides
- Mycotoxins (Aflatoxins and Vomitoxins)

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