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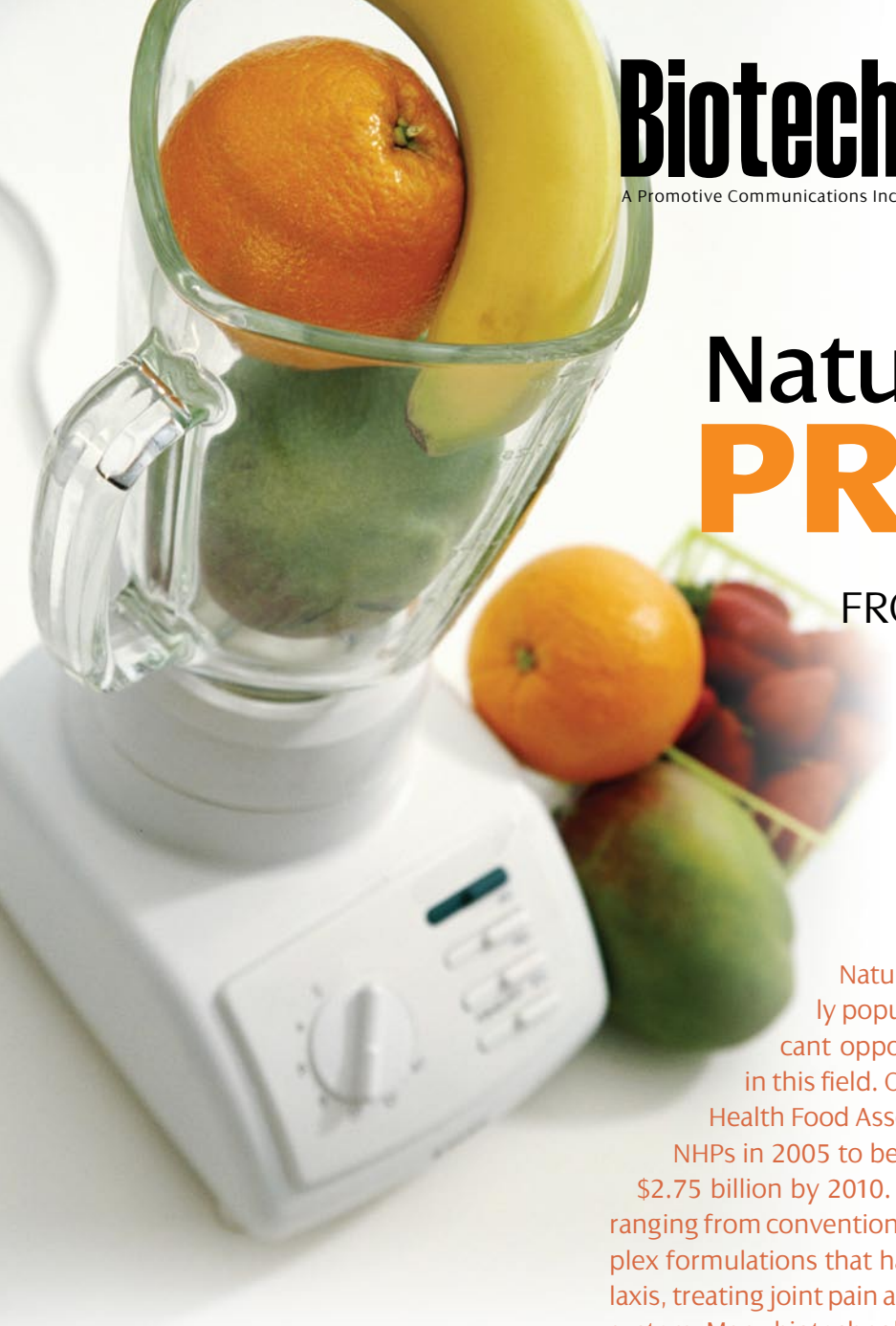

Natural Health PRODUCT

FROM PITFALLS TO PROFITS

By Laurence MacPhie

Natural Health Products (NHPs) are increasingly popular with Canadian consumers and significant opportunities exist to develop new products in this field. One study commissioned by the Canadian Health Food Association estimated the total retail sales of NHPs in 2005 to be $2.5 billion and are expected to grow to $2.75 billion by 2010. NHPs include a wide variety of products ranging from conventional vitamin supplements to relatively complex formulations that have been approved for migraine prophylaxis, treating joint pain and inflammation, or to boost the immune system. Many biotechnology companies are well positioned to enter the NHP market. However, companies should carefully review their activities to ensure compliance with government regulations and to identify any potentially valuable intellectual property.

The Regulatory Framework for NHPs

The increasing popularity and diversity of NHPs on the market has resulted in more scrutiny and regulation of NHPs by Health Canada. In 2004, a new framework for regulating NHPs under the Food and Drug Act was launched with the Natural Health Product Regulations (the "Regulations") coming into force. In developing the Regulations, Health Canada's intent was to cover a wide variety of health products available to consumers without first consulting a health care provider and obtaining a prescription. While previously many NHPs were simply sold as foods, under the Regulations NHPs are considered a special category of drugs and are subject to significantly tighter controls regarding their manufacture, labeling and distribution.

What Natural Health Products are Regulated?

Whether or not a product is classified as a NHP depends on both its ingredients and any health claims associated with the product. NHPs can include consumer products such as energy drinks, antiperspirants and sun protectants as well as products that are sold for use in the treatment or prevention of specific disorders or diseases.

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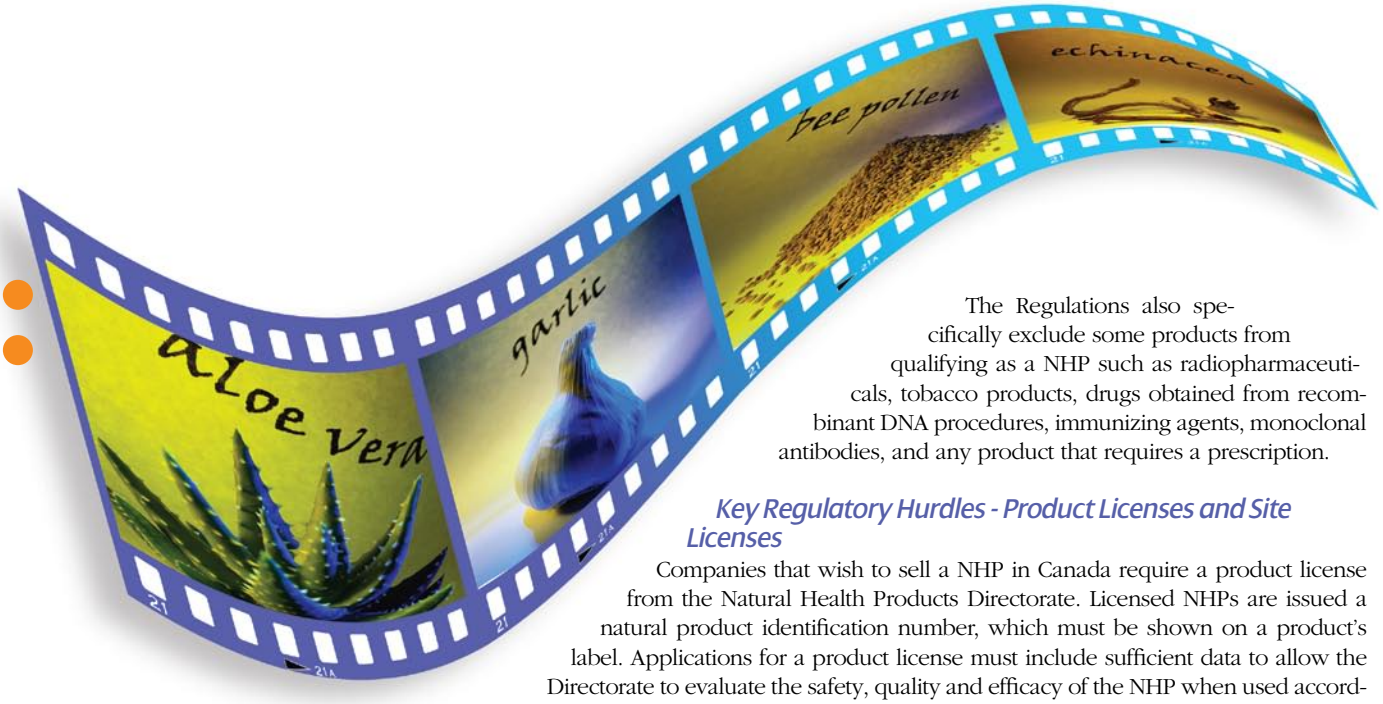

The medicinal ingredients in a NHP must be listed as "natural" substances under Schedule 1 of the Regulations. These include:

- a plant or plant material, an alga, a bacterium, a fungus or a non-human animal material
- any extract or isolate of the above
- vitamins
- amino acids
- essential fatty acids
- any synthetic duplicate of the above
- minerals
- probiotics

The Regulations also specifically exclude some products from qualifying as a NHP such as radiopharmaceuticals, tobacco products, drugs obtained from recombinant DNA procedures, immunizing agents, monoclonal antibodies, and any product that requires a prescription.

Key Regulatory Hurdles - Product Licenses and Site Licenses

Companies that wish to sell a NHP in Canada require a product license from the Natural Health Products Directorate. Licensed NHPs are issued a natural product identification number, which must be shown on a product's label. Applications for a product license must include sufficient data to allow the Directorate to evaluate the safety, quality and efficacy of the NHP when used according to the recommended conditions of use. The data that is required will vary depending on the composition of the product and the proposed health claim. Generally, all health claims associated with a NHP must be supported by scientific evidence such as clinical trials or references to reputable sources, such as product monographs, pharmacopoeias or peer-reviewed published articles. At least some of the data submitted in an application must reflect human use. Animal or in vitro experimental data may be submitted as part of the application but cannot form the basis for approval. When available, previous marketing experience (such as in the US) can also be submitted to supplement the evidence supporting a product's safety and efficacy.

When applying for a product license, remember that the regulations require the submission of evidence from all relevant sources, including both favourable and unfavourable data (if present). Also, be sure to carefully review the proposed NHP label to make sure it conforms with the Regulations before submitting an application.

Businesses that wish to manufacture, package, label or import a NHP for sale in Canada must also hold a valid Site License. These activities must be carried out in accordance with specific Good Manufacturing Practices (GMP) that are set out in the regulations. Importers that wish to apply for a site license must provide evidence that any foreign site associated with a NHP meet the specific Canadian GMPs. Accordingly, remember to investigate what information is available regarding foreign manufacturing or packaging sites when considering importing a NHP into Canada.

Bill C-51 and Enforcement of the Regulations

As part of the Food and Consumer Safety Action Plan, the federal Government recently tabled Bill C-51, which proposes amendments to the Food and Drugs Act that include a significant increase in fines for noncompliance with the regulations.

While the Bill has generated a significant amount of controversy, Health Canada has maintained that they will continue to be guided by the principle that the higher the risk to human health and safety posed by a NHP, the more immediate the compliance and enforcement action. Nevertheless, it appears that Health Canada will soon be taking a more aggressive approach to enforcing the Regulations, and that the consequences of noncompliance may also become more severe.

Navigating the licensing requirements for a NHP can take a significant amount of time and energy, especially given the backlog of applications before the Directorate. Try to avoid frustrating delays by carefully reviewing the Regulations during product development and applying for licenses as early as possible.

Gaining a Competitive Advantage Through Patent Protection

Until recently, there has been relatively little discussion of patent protection within the NHP community. In part, this may be due to the presumption that because NHPs are "natural" substances, they are somehow excluded from patentability. In fact, NHPs are patentable in Canada as along as they meet the legal requirements of novelty, non-obviousness and utility. While it is possible that natural substances and their properties are more likely to have been publicly disclosed such as to destroy novelty (and bar patentability), patent law does not distinguish between NHPs and other chemical products.

A NHP that is merely a combination of elements used for their known purpose (such as vitamin C and Echinacea for use in the treatment or prevention of colds) is not patentable. However, patent protection may be available for products that consist of a novel combination of elements that act to provide a surprising result or health benefit. Moreover, patent claims directed to new uses for a known product may also be permitted. While methods of medical treatment are not patentable in Canada, patents for novel compositions and for their use in the treatment of a particular disease or disorder are allowed.

One important point to keep in mind is that the level of evidence required to support a use claim before the Canadian Patent Office is generally lower than what would be required to support a health claim for a NHP Product License before the Directorate. For example, as long as a patent application includes sufficient data (such as in vitro data or animal studies) to allow a skilled person to soundly predict the usefulness of a substance in humans, human clinical data is not necessarily required.

Finally, biotechnology companies often have specialized knowledge with respect to the processing of specific plants, plant extracts or other "naturally" derived materials. It is worth remembering that patents may be available for methods of manufacture or for processes of extracting, isolating or synthesizing these substances.

Companies or individuals developing NHPs should have a patent strategy in place and consistentlly review their research and development activities to spot potentially valuable intellectual property. For Canadian companies wishing to generate investment or expand into the United States, a pending patent application is a useful asset that can showcase new technology, encourage investor confidence and facilitate growth.

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For more **NATURAL HEALTH PRODUCT** information visit our **Nutritional Products** Web Portal at **www.bioscienceworld.ca**