



## Council for Responsible Nutrition

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May 25, 2024

### VIA ELECTRONIC SUBMISSION

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### **Re: Respectfully request consideration of CRN and CRN Member Company comments for the Health-Canada Revised Consultation on proposed fees for natural health products**

The Council for Responsible Nutrition (CRN<sup>1</sup>) is the leading trade association for the dietary supplement, functional food and nutritional products industry, representing responsible manufacturers of dietary ingredients and of national brand name and private label dietary supplements and functional foods, many of which are multinational and already actively selling ingredients, finished products and services globally. CRN membership is made up of many companies that sell into Canada, as well as Canadian companies selling into the U.S. and beyond.

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<sup>1</sup> The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 200 dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit [www.crnusa.org](http://www.crnusa.org). Follow us on Twitter [@CRN\\_Supplements](https://twitter.com/CRN_Supplements), [Facebook](https://www.facebook.com/CRNSupplements), and [LinkedIn](https://www.linkedin.com/company/crn).

CRN and CRN Members have reviewed the revised fee proposal (March 27, 2024) for natural health products (NHPs) and our concerns persist on the potential impact on businesses; not only domestic Canadian companies, but more financially-impacted, multinational companies exporting value-added, and consumer-sought dietary supplements, and functional food products comparable to NHPs into Canada.

While the revised proposal includes reduced fees compared to the original proposal of May 2023, and the fee ratios are spread over seven years, this is not nearly enough. The current proposal is based on a broken system that looks to industry to fund the Natural and Non-prescription Health Products Directive inefficiencies. If it passes, it will still force many NHP brands off shelves and cause prices to skyrocket, especially those being imported into the Canadian NHP market.

CRN and CRN Members generally embrace the spirit of Health Canada's purpose, that is ensuring that all Canadians have access to safe, efficacious natural health products that are of high quality. Nonetheless, any regulatory updates must be done following proper processes and due diligence as established within the Natural Health Product Regulations and Food & Drug Act in close consultation with industry.

The consultation on proposed cost-recovery fees for natural health products includes fees for NHPs in three areas: (1) pre-market evaluation, (2) the right to sell and (3) site licensing. Although the Natural Products industry has not paid fees for regulatory activities since the inception of NNHPD in 2004, it is common practice in other Health Canada bureaus, including drugs and medical devices. While the Natural Products industry should pay reasonable fees for services rendered, it is important that NNHPD adhere to and improve on current review timelines and first implement the regulatory changes of the self-care framework before fees are put in place.

CRN has Canadian members, as well as many multinational members who do business in Canada, and invest in Canadian manufacturing and procurement of raw materials and ingredients. The new cost recovery program may negatively impact ongoing investment in Canada given the increased costs involved in operating on Canadian soil.

The dollar amount ascribed to the various fee areas are difficult to rationalize given the relative limited resources of many NHP companies, and the lower market-driven profit margins realized by natural health products and their ingredients that unfortunately do not share the same intellectual property protections or exclusivity on the market enjoyed by the pharmaceutical and OTC industries.

Unfortunately, the fee proposal will likely negatively impact Natural Health Product innovation, resulting in less choice for consumers, reduced sales and loss of Canadian jobs and manufacturers in the NHP space. Not only will innovation be stifled, and fewer new products brought to market, these high costs are likely to negatively affect research investment and limit Canadian competitiveness. And there will be a concomitant “trickle-down” effect as multinational companies who have traditionally offered NHP products to the Canadian market will need to pass the increased costs on to the Canadian consumer.

Additionally, it will increase the number of poor quality and / or illegal products being imported and available to Canadian consumers – it is thus imperative that any fee structure include a portion of the fees collected to be earmarked for enforcement activities.

Health Canada, to date, has refused to provide domestic and international stakeholders with the cost-benefit analysis, stating the Regulatory Impact Analysis Statement (RIAS) would only be made available once the regulations are finalized.

Modernization program activities and efficiencies have been completely cancelled including: enhanced IT applications; quality review of submissions and audit function; strengthening the review of efficacy data for products making claims for serious diseases; strengthening oversight of online advertising; and increasing capacity for processing and education.

The bottom line perspective that CRN and CRN Members voice is that the funds collected via the cost recovery proposal would fund a system in need of repair, however, the repairs need to be addressed first, followed by the implementation of an open, transparent, inclusive discussion with all stakeholders to ensure alignment with a process that is fair to the long term health of the Canadian Consumer and long-term viability of the Canadian Natural Health Product Industry.

CRN and CRN Members respectfully request that the Natural and Non-prescription Health Products Directorate consider our comments in the spirit in which they are being offered, as we recommend a delay in implementation of this cost recovery proposal so that industry and the NNHPD can work together to develop a more reasonable fee structure.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. Griffiths', with a long horizontal flourish extending to the right.

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