GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

PROPOSED FEES FOR NATURAL HEALTH PRODUCTS (NHP)

Proposed Fee Structure and Fee Amounts

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide EPA and DHA omega-3 industry, with a mission to increase consumption of EPA and DHA omega-3s around the world. The membership is built on a quality standard unparalleled in the market and members must comply with quality and ethics guidelines that ensure members produce quality products that consumers can trust. Our 170+ members represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands, including those companies selling products in Canada who would be directly affected by the proposed mandatory fees for pre-market evaluations (EVAL), site licences (SL) and rights to sell (RTS). If finalized, these fees have the potential to quickly reduce Canadian's access to marketed natural health products (NHPs) and cause significant harm to the industry.

GOED appreciates Health Canada's commitment to the Natural Health Products Regulations (NHPR), both pre- and post-market activities, of the Food and Drugs Act (FDA), which helps Canadians access a wide range of safe, effective and high-quality NHPs. While we are not opposed to the implementation of cost recovery for NHPs, we are opposed to cost recovery as extensive as that currently proposed by Health Canada. Given the lower revenue from NHPs, compared to human drugs and medical devices, proposing a fee structure that aligns across health products is shortsighted. What is the incentive to pay almost $60,000 to apply for an NHP approval when most formulas cannot be patent protected.

While the Food and Drugs Act (FDA) provides Health Canada the authority to set and charge health product fees associated with NHPs, doing so as proposed would undoubtedly have unintended consequences including, but not limited to reduced innovation and stagnation in the NHP industry. If companies selling NHPs are forced to pull out of Canada, this will result in decreased NHPs available to Canadians. For those NHPs that remain on the market, the burden of increased costs will inevitably be passed along to consumers, leaving many unable to afford the products they rely on for their well-being. This means Canadian's ability to participate in preventative healthcare will be drastically hindered.

Canada is already one of the most highly regulated countries when it comes to natural products. Natural Health Products Numbers (NPNs) are only granted to products that meet Health Canada's strict standards for safety, efficacy, and quality. While Health Canada's stated goal is to promote access to safe, effective, and high-quality NHPs for Canadian consumers, it remains to be seen how this proposal will accomplish this goal. NHP consumers are price sensitive and they will stop purchasing NHPs if the costs become too high.

GOED will now address a select number of specific issues within **Proposed Fee Structure and Fee Amounts.**

Costs Associated with Increasing Staff

The proposed costs associated with increasing staff seems excessive for pre-market evaluation (EVAL) services. Even with additional reviewers, Health Canada is proposing to extend the review period. The

expectation should be to first meet established service delivery standards. It is our opinion that increasing staff for billing/invoicing processes are unnecessary and should be minimal at best as all accounts receivable activities could be consolidated across Health Canada for the products under the FDA, including: NHPs, food, drugs, medical devices and cosmetics.

Accounting/Billing Processes
Billing/invoicing processes and capabilities, including staffing already exist for other cost recovery efforts (e.g. drugs, medical devices), so why is the Natural and Non-prescription Health Products Directorate (NNHPD) creating something new instead of consolidating all billing/invoicing activities under one umbrella, which would result in minimal, if not non-existent, increases in costs? Consolidating accounts receivable is a standard practice for any corporation.

Pre-Market Evaluations
Industry is constantly looking to offer Canadian consumers valuable and beneficial products that contribute to the maintenance or improvement of overall health. The proposed application fees are high and if an application is rejected, the cost to keep resubmitting will eventually become too burdensome to industry and ultimately result in the long-term decline of new and innovative products from entering the Canadian market. To help offset these costs, GOED proposes that NNHPD provide a 90% refund for rejected submissions (whether class I or Novel Class III).

The extremely high costs ($7,209 - $58,332) for class III product licence applications (PLAs) will stifle innovation necessary to bring new products to the market. In addition, it will have a negative impact on research initiatives and competitiveness to the Canadian market.

The excessive proposed fees are unfair, unreasonable and could be detrimental to Canadian businesses. 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 the implementation of fees.

Site Licence (SL) Fees
The NNHPD is considering imposing yearly site license (SL) fees that are not part of the cyclical renewal process. Part of this yearly fee is an audit/site inspection; therefore, we do not understand why fees should be levied for adding manufacturing sites. These fees should be included in the yearly audit and licence fee.

GOED encourages Health Canada to consider modifying the proposed SL fees so they are based on the number of NHPs manufactured at a specific site. The more NHPs manufactured, the higher the SL fee.

Right to Sell (RTS) Fee
We believe the RTS fee should be for marketed NPNs only, not active NPNs. Companies often have active NPNs that are not being used for various reasons (e.g., a class III NPN that will be marketed in the future). An RTS fee of $542 per NPN is very high given that some companies have many products on the market.

Proposed service standards and penalties for missed standards
No comments

Proposed mitigation measures, including small businesses
We encourage Health Canada to adjust the proposed cost recovery costs to reflect more accurately the size and scope of the NHP industry.

There is a risk that small and medium-sized businesses will not be able to afford the proposed fees and it remains to be seen how companies will manage the costs, but there's a good chance that they will ultimately try to pass them along to consumers. Should this happen, Canadian consumers may end up ordering non-compliant products from outside of Canada, making it more difficult or impossible for companies who currently invest in Canadian compliant products to continue to do so.

We request Health Canada to remove affiliates (i.e. parent companies) from the definition of small and medium-sized enterprise (SME), because this can result in a small business being required to pay more money. Standalone entities maintain their own balance sheets and are less likely to be able to absorb the costs associated with being classified as more than a small business.

Proposed timeline for implementation (April 1, 2025)
The current cost recovery proposal for NHPs is in addition to the implementation of pending, not to mention significant, labelling changes (*Regulations Amending the Natural Health Products Regulations: SOR/2022-146*), which come into force June 21, 2025. The labelling changes alone are considered by many companies to be a financial burden. While significant due diligence went into the cost recovery proposal, GOED encourages Health Canada to put the proposal on hold and to revisit it once the pending labelling changes have been implemented.