



**NNHPD Monograph Consultation:
Multiple Ingredient Fixed Oil Products –
Oral**

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Bad Science Watch

Bad Science Watch is an independent Canadian consumer protection organization dedicated to promoting good science in public policy.

The following was prepared by volunteers and represents what we believe to be an honest, fair, and science-based evaluation. We are an independent body that is funded by private donations and we do not represent any corporate interests.

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Summary

This is a submission in response for the Natural and Non-prescription Health Products Directorate's (NNHPD) public consultation of a revised monograph for "multiple ingredient fixed oil products – oral" (Health Canada, 2014). Due to the short consultation time for this public consultation, released simultaneously with another new consultation on soy flour, this committee had only time to consider one monograph. This runs counter to Health Canada's promise for regulatory openness and transparency.

This monograph, but leaving the "durations of use" and "contraindications" fields blank suggests that Health Canada feels these products are inherently safe and require no warnings. We found evidence that instead shows that these products do represent a risk to the consumer when taken in combination with other products and for longer duration. As well, there are known risks for anaphylactic allergic reactions to many of the products listed in this monograph, and there are no manufacturing standards indicated to ensure that the product is produced without these known allergens. Almond oil, an oil under the "tree-nut" category as well as borage, safflower, and coconut oil are examples.

We found indications that several products, including borage oil and evening primrose oil, should have pregnancy warnings on the label. We also had concern with the lack of external resources cited by Health Canada in the document. As well there are a number of uncited references listed. It speaks very poorly of the review process of at Health Canada's NNHPD that they do not cite the sources for their conclusions. This, combined with the obvious missing information listed above, suggests strongly that the review process should not only be undertaken with greater scrutiny for this monograph, but that the entire process needs a thorough revision to ensure the safety of Canadians.

Review

Consultation Time Period

Health Canada's Foods and Therapeutic Products directorates normally give a 42 to 60 day consultation period; hence the 30-day review period for this proposed monograph and a second (soy flour) released simultaneously on January 15, 2015 is seriously lacking Health Canada's promise for regulatory openness and transparency. The short time period and the release of two proposed monographs have prevented us from adequately reviewing both due to limited resources; hence, we have had to limit our review to this proposed monograph.

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Main Concerns

Three issues were readily apparent:

- Directions for use,
- Duration of use, and
- Contraindications.

In each of these sections, the text stated “no statement required.” This statement suggests that NNHPD has no safety considerations for these products that need commenting upon. In examining other sources of information such as the Natural Medicines Comprehensive Database (NMCD, 2015), it was determined that the monographs in that database recommend that several of these products should not be used in combination with other herbals due to the risk of adverse reactions. In a number of instances, the NMCD monographs did not provide any indication for the dose or duration of use which would suggest that long term use is either contraindicated or that there is insufficient information to establish upper limits for their use. A number of NMCD monographs state that their use should be suspended prior to surgery as there may be an increased risk for bleeding.

This lack of statements further suggests that there are no risks for serious adverse events if these products are used with other health products. Herb-drug interactions are well documented. As an example, evening primrose oil is known to affect cytochrome P450 2C19-mediated metabolism (Zou et al, 2002) which is required for the activation of Plavix (clopidogrel), a heart drug. Interactions with other health products have also been reported by NMCD for: sweet almond, borage, safflower, sea buckthorn, krill, evening primrose, black currant.

Known Adverse Reactions

This section only mentions krill and squid oil hypersensitivity. Almonds, listed under “tree nuts”, are a Health Canada priority allergen, but this was not one of the products listed specifically. In addition, allergic (including anaphylactic) hypersensitivity is also known for borage, safflower, and coconut. Does this mean that the NNHPD is willing to let therapeutic almond and other oils be marketed without allergen labelling and without any requirement that the oil be highly refined so that no allergen remains in the product?

Specifically, our interpretation is that all the monograph requires for almond oil is that “The finished product specifications must be established in accordance with the requirements described in the NNHPD Quality of Natural Health Products Guide.” The NNHPD Quality of Natural Health Products Guide (Health Canada, 2013) has little to say on the subject with a limited mention of allergens, referring to sulphite and gluten, and nothing specific for almond oils. Thus, there appears to be no requirement that



almond oil (or any oil) be refined to a purity level that ensures no antigen present. Anaphylaxis Canada lists tree nut oils as a possible source of allergen and hence extreme caution must be undertaken (Anaphylaxis Canada, 2013).

This review was not able to take into consideration any potential interactions with conditions, diseases or laboratory tests other than bruising and bleeding risk, and blood glucose control. Borage oil was found by the NMCD reviewers to interfere with bruising and bleeding times and this could lead to a serious adverse event during surgery or when the product is combined with pharmaceutical anti-platelet medications. Sweet almond oil can decrease blood glucose levels and may interfere with blood glucose control in patients with diabetes requiring dosing adjustment for insulin or oral hypoglycemic agents (NHCD, 2015). These risks are likely common in the target population for intended indications and should be considered by Health Canada in any evaluation of safety. Even with our preliminary search we found these risks and we are concerned that they were ignored or missed by Health Canada.

Cautions and Warnings

Cautions and Warnings only suggests that women who are pregnant or breast feeding, talk with physician prior to using hemp seed, sea buckthorn, krill, blackcurrant, squid. The NMCD monographs clearly state that there is insufficient reliable information for sweet almond, borage, safflower, coconut oil, evening primrose and these should be avoided during pregnancy and/or lactation. Undoubtedly, this cautionary statement may be found with other products listed in this proposed monograph.

Recommended uses, Table 2

We are concerned that many of the references for this recommendation are not current and that the principal reference for NNHP 2014 states “internal evidence”. How has this value been determined and would it meet the general principles given in the “The Regulatory Transparency and Openness Framework for Health Canada”? Where can the documentation supporting this determination, and hence decision, be found?

References

There were an extensive number of uncited references. Some of the cited references were incomplete. The citations lack a critical review of the current scientific and medical literature on the safety and efficacy of these substances. The EFSA guidelines are not sufficiently current to establish that these fatty acids are efficacious in these multiple ingredient fixed oils or that these multiple ingredient products are safe where we have noted several serious safety issues in unblended products, let alone any combination product.

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Conclusion

Does NNHPD have credible, scientific information to evaluate the long term safety of these products for these indications under these unlimited conditions? Particularly when they seem at odds with NMCD monographs. Has any Health Hazard Evaluation been undertaken, as is common within this Branch? If so, this information should be made publically available for evaluation.

The limited review period has precluded a thorough evaluation, but the above safety issues involving a limited number of products suggest that there are serious health risks involved within this broad monograph. Any of these concerns warrant further evaluation by Health Canada, and together they reflect a real or perceived bias favouring industry without meeting the mandate of Health Canada.

According to the Regulatory Transparency and Openness Framework for Health Canada, a response to our concerns and others in this consultative review should be forthcoming. If Health Canada proceeds with this monograph, we would be particularly interested in the details on how and why this decision was reached as it will put the health and wellbeing of Canadians at risk.

References

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