The Compositional Guidelines Officer
Office of Complementary Medicines
Therapeutic Goods Administration
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Dear Compositional Guidelines Officer

CHC Submission – Draft Compositional Guideline for Fish Oil – Natural

Thank you for the opportunity for the complementary healthcare industry to provide comment on the draft compositional guideline for 'Fish Oil – Natural'. The Complementary Healthcare Council (CHC) provides the following comments for consideration prior to finalisation of the draft:

- The CHC would like to suggest that the name of the ingredient in the guideline be linked to the substance's Australian Approved Name (AAN) for industry's benefit. This could be included in '*Name the ingredient*' section or as a stand alone section.

- Given that residual solvents are a legislated requirement to test for, and that fish oil is unlikely to be solvent extracted, the CHC does not consider it necessary to include this specification in the guideline.

- The CHC notes that microbiological standards are the responsibility of the manufacturer/sponsor therefore how these results are obtained should be the responsibility of the TGA licensed manufacturer. The CHC therefore suggests the reference to the Therapeutic Goods Order (TGO 77) for microbiology testing be incorporated into the guideline as a comment/reminder rather than being presented as a test specification.

- The CHC notes that the odour characteristic is described as 'fishy' – given that de-odourised fish oil may not have a 'fishy' scent and therefore suggests this be noted.

- The acid value outlined in the guideline has acceptance criteria of NMT 2.0. The CHC points out that the BP and the USP have limits of NMT 0.5 and 3.0 respectively. The CHC requests justification for how the specification was determined.

- Under the method reference for assaying, the CHC notes that the test method for *Ph. Eur* Method 2.4.29 states 'the methods applicable to triglycerides or ethyl esters and the results are expressed as triglycerides or ethyl esters'. The CHC questions why the proposed limit is expressed as methyl esters and requests further justification for how the limits were derived. Furthermore, the original guideline states triglycerides which are also specifically required to be stated as such on the label for a listing application.

  The use of methyl esters as the content amount will create confusion for consumers and healthcare professionals if this becomes the requirement for labelling. Noting, for example, that the Australian Heart Foundation is recommending a specific amount of combined DHA and EPA for cardiovascular

health which is based upon the triglyceride amount, expressing methyl esters will be inconsistent; the CHC also points out that triglycerides are also reflected in the 'Recommended Dietary Intakes'.

The CHC also draws to your attention that the fish oil monographs within the BP and Ph. Eur state the EPA, DHA and omega-3 content to be expressed as triglycerides while the USP states that the EPA, DHA and omega-3 content to be expressed as free fatty acids – the CHC considers the requirement to express methyl esters to be out of step internationally.

In addition, the CHC points out that if products are required to express EPA and DHA as methyl esters rather than percentages, there will be labelling implications for industry; given there are numerous fish oil products available on the Australian market, the CHC believes this would have a significant impact to industry and should be carefully considered before finalisation of the guideline.

Given the above comments, the CHC recommends that triglycerides be clearly stated within the compositional guideline so that the assay section reads 'Sum of EPA and DHA NLT 22.0% triglycerides, Total omega-3 acids NLT 26% triglycerides'.

- The CHC notes that the method Ph. Eur 2.8.13 for Pesticides residue does not quote the actual qualitative and quantitative method analysis and only provides the limits that are applicable. The CHC does not consider there to be clear guidance for industry on how to perform the analysis and suggests this be rectified.

- The USP reference for Dioxins, furans and polychlorinated biphenyls (PCBs) states No. 1613 revision B and No. 1668 revision A of the Environment Protection Agency. The CHC notes that these methods are not readily available.

If you would like to discuss any matters within this submission further, please do not hesitate in contacting me.

Yours sincerely

Kristy Tomas
Scientific & Technical Manager

31 May 2010