

FOR IMMEDIATE RELEASE

Tackling Health Canada's Regulation of Oil of Oregano-derived Carvacrol

Toronto, Canada, September 12, 2011 - Health Canada has taken a strong position to evaluate the risk associated with the human intake of natural health products (NHPs) containing oil of oregano providing > 0.22 µg/kg body weight/day or 15.4 µg/day total carvacrol. In addition, Health Canada has begun sending Section 16 notices to manufacturers and distributors of oil of oregano to gather information on this issue.

Dicentra has reason to believe that the Natural Health Product Directorate (NHPD) of Health Canada is not aiming to undertake any extreme measures, but rather intends to work with the industry to explore possible solutions in the evaluation of this product. For years Dicentra's commitment to this effort extends far beyond a client service mandate. Every available option has been and will continue to be explored with Health Canada.

Currently carvacrol is credited with being the active ingredient in oil of oregano for preventing upper respiratory infections. Thus, most oil of oregano products sold in Canada contain carvacrol at 60 - 80 % oregano oil. Assuming oil of oregano products contain 1:3 oregano oil to olive oil (as a diluent), each drop (~26 mg) of product would provide ~ 6.5 mg oil of oregano and 3.9 – 5.2 mg carvacrol. However, without re-formulation, current oil of oregano products would need to adjust dosages to provide 19.5 - 25.6 µg/day oregano oil/day to comply with Health Canada's current regulations.

Given the limited availability of safety data surrounding carvacrol intake in humans, safety is Health Canada's primary concern. Thus, there are three feasible means for addressing the government's position. First, carvacrol could be removed from the oregano oil used within current oil of oregano products. Despite carvacrol being credited as the active ingredient that facilitates efficacy of oregano oil for respiratory infections, scientific evidence has yet to substantiate carvacrol's therapeutic effects. Second, Canada's position on carvacrol could be challenged using consumer data that corroborates the safety of oil of oregano-derived carvacrol at levels > 0.22 µg/kg body weight/day.

The third option, and likely more effective, is to produce the required safety data via preclinical and clinical studies. The latter requires a substantial financial commitment. However, upon the formation of an alliance between companies that provide oil of oregano to the Canadian market, the acquisition of safety data for carvacrol is feasible.

It remains to be seen whether this matter will spur the creation of such an alliance. For the industry to take no further action could mean a loss in sales for manufacturers of NHPs across

Canada as well as the loss of entire businesses. One industry member commented “Oregon Oil has been sold for over 25 years to millions of people in the US and Canada with no reported issues. This is a favourite product for many consumers and health food stores. If any potential product withdrawal can cause a strong reaction this is it.”

The Canadian Health Food Association (CHFA) has responded to this issue by facilitating further discussions with industry members and Health Canada. For more information and details on how you can participate please go to www.chfa.ca

Dicentra will continue to monitor Health Canada’s position on carvacrol and remains committed to providing regulatory and scientific solutions for continued business growth in this market.

About Dicentra

Dicentra is a leading international scientific and regulatory consulting firm with specialized expertise in the areas of natural health products, dietary supplements, foods, beverages, cosmetics and OTCs. For years, we have been helping clients resolve complex scientific issues, develop safe and effective market-leading products, and facilitate timely regulatory global approvals. Dicentra provides regulatory and scientific solutions for business growth you can trust. For more information go to www.dicentra.com

Contact:

For more information please contact:
Lydia Hunziker at 416 361 3400 x 229 or email at lydia@dicentra.com

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