Substantiation of supplement claims for [redacted] products containing myo-inositol in sufficient quantity for the recommended dosage to meet the claimed effect.

Myo-inositol supplementation supports hormonal balance by promoting normal glucose metabolism and testosterone levels, thereby improving ovarian function, egg quality, and menstrual cycle regularity.

A deficiency in inositol or its isomers may compromise otherwise healthy glucose levels (Pundir 2017, Regidor 2019). Further, women with suboptimal glycemic parameters have shown increased urinary clearance of inositols and reduced endogenous inositol (Baillargeon 2008). Supplementation with myo-inositol, a naturally-occurring inositol isoform, has been shown to support normal glucose metabolism (Bevilacqua 2018, Gateva 2018, Rocha 2019).

Recent literature reviews and meta-analyses have validated the efficacy of inositols in women with suboptimal glycemic parameters (Arentz 2017, Bevilacqua 2018, Lagana 2017, Pundir 2017, Rocha 2019, Sortino 2017, Unfer 2017). In a 2019 literature review, the effects of myo-inisotol was found to support normal glucose activity in the target organs of women, including the ovaries (Rocha).

The promotion of normal testosterone levels has been associated with improved metabolic profiles and glycemic parameters in several studies with myo-inositol supplementation (Artentz 2017, Lagana 2017, Pundir 2017, Unfer 2017). Testosterone production may increase when an excess of circulating glucose is present (Lagand 2017). Myo-inositol supplementation supports hormone balance by promoting normal glucose metabolism and testosterone levels.

Elevated testosterone levels may lead to anovulation. As previously mentioned, myo-inositol helps to re-establish hormonal balance, in part by improving testosterone levels, and subsequently positively effecting ovulation (Lagana 2017). In a 2017 literature review including 24 randomized-controlled trials and a 2017 meta-analysis including 10 randomized-controlled trials, inositol supplementation supported normal ovulation in women (Arentz, Pundir). Further, a 2018 literature review showed that myo-inositol helped improve ovarian function without side effects (Gateva). Furthermore, in a 2019 observational study, 70% of women (n = 3602) had restored ovulation when taking 2000 mg myo-inositol with 200 µg folic acid twice daily for 2-3 months compared to 13% in the placebo group (Regidor). The recent research suggests, therefore, that inositol and myo-inositol improve ovulation and ovarian function.

In addition to restored ovulation, oocyte maturation and pregnancy was also improved in this 2019 observational study (Regidor). These recent findings are supported by earlier literature reviews (Gateva 2018, Unfer 2012). For example, myo-inositol improved oocyte count and quality in a 2018 literature review summarizing the physiological roles of inositols (Gateva 2018). Likewise, a review of randomized-controlled trials demonstrated that myo-inositol supplementation in women improved oocyte quality as one of several positive effects for supporting fertility (Unfer 2012).

Some research also suggests that inositol and myo-inositol supports hormonal balance by helping to re-establish a regular menstrual cycle (Pundir 2017, Troisi 2019). A 2017 meta-analysis of 10 randomized-controlled trials examined inositol’s effect on menstrual cycle regulation in women. Inositol

was associated with an increased frequency of menstrual cycles compared to placebo (Pundir). Further, a 2019 prospective case-control study administered myo-inositol (1.75 g), d-chiro-inositol (0.25 g), and glucomannan (4.0 g) daily to 15 women with irregular menstrual cycles or 15 control subjects for three months. At the study's conclusion, although only 27% of the women in the treatment group reported having regular menstrual cycles, they all reported some kind of improvement in menstrual cycle regularity (Troisi).

Doses of 200 - 4000 mg daily of inositol and its isoforms were shown safe and effective; however, a daily dose of 2000 mg daily or twice daily were the most commonly used treatment doses (Artini 2013, Ciotta 2011, Regidor 2018, Troisi 2019).

Myo-inositol is a therapeutically important ingredient with proven benefits to human health. A review of the research demonstrates that myo-inositol supplementation supports hormonal balance by promoting normal glucose metabolism and testosterone levels. Myo-inositol also helps improve ovarian function, egg quality, and menstrual cycle regularity.

The preceding literature analysis reasonably substantiates the following claims for the use of myo-inositol as a dietary supplement ingredient:

1. Supports hormonal balance
2. Supports ovarian function
3. Supports egg quality
4. Supports a healthy menstrual cycle

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May 1, 2020