

## TABLE OF CONTENTS

### **Qualified Health Claim Petition for Xangold® Lutein Esters**

Table of Contents.....	2
Introduction and Purpose .....	4
<b>A) PRELIMINARY REQUIREMENTS FOR HEALTH CLAIMS.....</b>	<b>8</b>
1) 21CFR§101.14(b)(1) : Dietary intake of lutein or lutein esters is associated with reduction in two diseases of the eye affecting the general U.S. population .....	8
2) 21 CFR §101.14(b)(3)(i): Lutein esters contribute and retain nutritive value in conventional foods .....	12
3) 21 CFR §101.14(b)(3)(ii) Lutein esters are safe and lawful under the FDCA.....	15
<b>B) SUMMARY OF SCIENTIFIC DATA.....</b>	<b>18</b>
1) Changing Dietary Patterns and Lutein Esters Intake.....	18
2) Xangold ®Lutein esters conforms to the definition of “substance”in 21CFR§101.14(a)(2).....	20
3) Chemical/Physical/Biological Properties of the Lutein Esters: Lutein and Zeaxanthin.....	20
A. Chemical Properties.....	21
B. Physical Properties.....	21
C. Biological Properties.....	21
1. Light Filtration: Chromatic Aberration .....	21
2. Membrane Properties .....	22
3. Anti-oxidation and Pro-oxidation.....	23
4. Role of Oxidation in Cataract Formation .....	26
5. Bioavailability of Lutein Esters.....	27
4) Role of Lutein Esters in Improving Macular Pigment Density and reducing the incidence of Age-Related Macular Degeneration.....	28
A. Observational and Prospective Studies on Populations.....	28
B. Case Control Studies.....	34
C. Intervention Trials.....	40
5) Role of Lutein Esters in Reducing the Incidence of Cataracts .....	43
A. Observational/Prospective Studies .....	43
B. Case Control Studies.....	46
C. Intervention Studies .....	48
6) Conclusions on Available Scientific Data .....	49
7) Additional Issues To Address In Qualified Health Claim Petitions.....	50
A. Foods supplemented with Lutein esters would provide a meaningful amount of lutein and zeaxanthin in the diet .....	50
B. Public Health Benefit.....	51

8) Summary and Conclusions.....	54
<b>C) ANALYTICAL METHODS/RESULTS.....</b>	<b>56</b>
<b>D) HEALTH CLAIM STATEMENT .....</b>	<b>57</b>
<b>E) ATTACHMENTS .....</b>	<b>58</b>
<b>F) ENVIRONMENTAL IMPACT.....</b>	<b>59</b>
<b>G) EXPERT PANEL CONSENSUS STATEMENT .....</b>	<b>60</b>
<b>H) CERTIFICATION.....</b>	<b>61</b>
<b>I) REFERENCES .....</b>	<b>62</b>