

OPPORTUNITIES FOR OMEGA-3 PRODUCTS

Prepared by:

CPL Business Consultants
Innovation Centre, Milton Park, Abingdon,
Oxfordshire, OX14 4RY
Tel: +44 1865 257 057, info@cplconsult.com,
www.cplconsult.com

Dr Robert Harwood
Dr Steve Lisansky
Dr Esther Hunter
Dr Michael Lee
Ms Megha Chugh
Ms Karen Kolodziej

TABLE OF CONTENTS

VOLUME 1

OBJECTIVE AND BACKGROUND..... 1

METHOD 1

CLIENT’S QUESTIONS 2

 DEVELOPING A MARKET ENTRY STRATEGY 2

 PRODUCT PRICING AND THE MARKETING APPROACH..... 3

 KEY SUCCESS FACTORS 5

 BARRIERS TO ENTRY 5

 POTENTIAL PARTNERS 5

 PLANT CAPACITY 7

PRINCIPAL FINDINGS AND CONCLUSIONS 9

 MARKETS..... 9

 COMPETITION..... 10

 DIETARY SUPPLEMENTS..... 11

Introduction..... 11

Omega-3 supplements 12

 FUNCTIONAL FOODS 13

 PHARMACEUTICALS 15

Introduction..... 15

Raw materials..... 16

Omega-3 pharmaceuticals..... 16

Future prospects..... 18

 ALTERNATIVE PRODUCTS 19

 REGULATORY..... 20

RECOMMENDATIONS..... 21

MARKETS 22

 MARKET ESTIMATES 22

 RAPID MARKET GROWTH..... 23

 MARKET DATA SOURCES..... 25

 MARKET DRIVERS 26

Growth promoters 26

Growth inhibitors 27

 VALUES..... 29

 VOLUMES..... 36

 PRICES 40

Prices obtained from contacts 40

Prices by product type 44

OVERVIEW OF CONTACTS’ OPINIONS 45

 MARKETS..... 45

Market Growth 45

Market Drivers and Constraints..... 45

Market Trends 47

New Formats 49

 PLAYERS AND PRODUCTS..... 50

Omega-3 Companies 50

Distributors 59

End users 60

Supplements..... 64

Pharmaceuticals..... 65

Regulations..... 66

BARRIERS TO ENTRY	69
KEY FACTORS FOR SUCCESS	70
<i>General</i>	70
<i>Key Factors for Success in Food</i>	72
STRATEGY.....	73
<i>Partnerships</i>	74
<i>Marketing</i>	74
<i>Capacity</i>	74
CLIENT'S CLAIMS	75
<i>Traceability</i>	75
<i>Reflux</i>	76
<i>Amines</i>	77
<i>Hygiene</i>	77
<i>Purity</i>	78
<i>Halal/Kosher</i>	78
COMPETITION	80
COMPLETE MANUFACTURERS' PRODUCT LISTING	80
COMPANY SUMMARIES	102
MAJOR GLOBAL FISH OIL REFINERS	110
<i>29 companies</i>	
MANUFACTURERS' B2B MARKETING CLAIMS	236
<i>Claims about product qualities and processing skills</i>	236
<i>Claims about accreditation, certification, health and safety</i>	253
PRODUCTION FACILITIES	261
DIETARY SUPPLEMENTS.....	264
DIETARY SUPPLEMENTS - OVERVIEW	264
<i>Product Categories</i>	265
<i>Product and Brand Differentiation</i>	265
<i>Market Drivers</i>	265
<i>Success Factors</i>	266
<i>Barriers to Entry</i>	267
<i>Overview of the Global Omega-3 Dietary Supplements Market</i>	268
<i>Benefits of Omega-3 Supplements</i>	269
<i>Origin of Fish Oils</i>	270
<i>The supplements supply chain</i>	271
US – OMEGA-3 SUPPLEMENTS	272
<i>12 products</i>	
EUROPE AND ROW – OMEGA-3 SUPPLEMENTS	302
<i>12 products</i>	
CURRENT PRODUCT CLAIMS & CLIENT'S PRODUCTS.....	325
<i>Product claims compared to Client's product properties</i>	330

VOLUME 2

FUNCTIONAL FOODS	331
FUNCTIONAL FOODS - OVERVIEW	331
<i>Consumer Need for Omega-3 Food Products</i>	332
<i>Omega-3 Functional Food Categories</i>	332
<i>Benefits of Omega-3 Functional Foods</i>	333
<i>Success Factors</i>	333
<i>Market Presence</i>	334
FUNCTIONAL FOOD PRODUCT LAUNCHES	336
EXAMPLES OF FUNCTIONAL FOOD RETAIL PRODUCTS.....	339
<i>32 products</i>	
PHARMACEUTICALS	367
PHARMACEUTICAL INDUSTRY OVERVIEW	367
OMEGA FATTY ACIDS	368
<i>Market</i>	368

<i>Players & Products</i>	369
<i>IP & Clinical Trials</i>	372
COMPANIES WITH AN INTEREST IN O3S AS DRUGS.....	373
<i>4 companies</i>	
COMPANIES CONSIDERING GENERIC VERSIONS OF OMEGA-3 DRUGS	389
<i>3 companies</i>	
O3S AS PRENATAL DRUGS	392
<i>1 company</i>	393
NON-PRESCRIPTION, HIGH END DIETARY SUPPLEMENTS	393
<i>4 companies</i>	
PHARMACEUTICAL PATENTS.....	412
CLINICAL TRIALS FOR EPA AND DHA.....	428
NEWS , SCIENTIFIC PAPERS AND PRESENTATIONS.....	447
<i>19 articles</i>	
OVERVIEW OF THE GLOBAL PHARMACEUTICAL INDUSTRY.....	476
MARKET.....	476
MARKET TRENDS	479
THE DRUG DEVELOPMENT PROCESS.....	481
<i>Cost of developing a new medicine</i>	481
<i>Drug development and the conduct of medical research</i>	482
<i>Clinical trials</i>	484
<i>Success rates in Drug Development</i>	487
<i>The promotion of drugs</i>	487
<i>Market Penetration for New Drugs</i>	488
INTELLECTUAL PROPERTY PROTECTION	489
<i>Procedures for Drug Approval</i>	490
PLAYERS	490
<i>13 companies</i>	
THE PHARMACEUTICAL INDUSTRY BY REGION.....	507
<i>The US Pharmaceutical Industry</i>	507
<i>The European Pharmaceutical Industry</i>	508
<i>US vs. Europe - Competitive Comparison</i>	530
<i>The Pharmaceutical Industry in the ROW</i>	532
ALTERNATIVE COMPETING PRODUCTS.....	541
ALGAE OMEGA-3 PRODUCT MANUFACTURERS.....	541
<i>3 companies</i>	
TWO ENHANCED FLAX OIL PRODUCERS	555
<i>2 companies</i>	
KRILL OIL	562
<i>Key trends and developments</i>	562
<i>Competitive Factors</i>	563
<i>4 companies</i>	
REGULATORY - NUTRITION CLAIMS, HYGIENE	579
SUMMARY.....	579
UK REGULATIONS	580
<i>Food Standards Agency</i>	580
<i>Novel foods</i>	580
<i>Nutrition and health claims</i>	581
<i>Nutrition claims</i>	581
<i>Health claims</i>	581
<i>Labelling</i>	582
<i>Food law enforcement</i>	583
REGULATIONS (EC) No 1924/2006 ON NUTRITION AND HEALTH CLAIMS MADE ON FOODS	583
<i>Article 13 Nutrition and health claims</i>	583
<i>Article 13 overview of deadlines</i>	585
<i>Criteria for screening of Article 13 health claims</i>	586
<i>Article 14 Disease risk claims</i>	586
<i>Health claims deadline will not be met</i>	586
ARTICLE 14 CLAIM EXAMPLES.....	587
<i>I omega kids®/Pufan 3 kids® and calming</i>	587

<i>SI omega kids®/Pufan 3 kids® and serenity</i>	588
<i>I omega kids®/Pufan 3 kids® and vision</i>	589
<i>I omega kids®/Pufan 3 kids® and concentration</i>	590
<i>I omega kids®/Pufan 3 kids® and mental development</i>	591
ARTICLE 14 INFANT HEALTH CLAIMS	592
<i>EFSA on omega-3 claims: yes to eye health, no to brain</i>	592
<i>EFSA opinion on DHA and ARA and visual development</i>	594
<i>EFSA opinion on Enfamil® Premium and brain development</i>	596
OPINION ON NUTRITION CLAIMS FOR OMEGA-3 FATTY ACIDS	597
<i>Summary</i>	597
<i>Omega-3 fatty acids claims</i>	598
<i>Monounsaturated fat claim</i>	598
<i>Polyunsaturated fat claim</i>	599
<i>Unsaturated fat claim</i>	599
HYGIENE REGULATIONS ANNEX III - FISHERY PRODUCTS	601
<i>Chapter I: Official Controls of Production and Placing on the Market</i>	601
<i>Chapter II: Official Controls of Fishery Products</i>	604
<i>Chapter III: Decisions after Controls</i>	604
<i>Postponement of hygiene regulations</i>	605
EU WORKING GROUP ON FISHERIES AND AQUACULTURE	606
US DIETARY SUPPLEMENT REGULATIONS	608
ONC REGULATORY APPROVALS.....	608
<i>United States</i>	608
<i>Fish Oils and Capsules in Canada</i>	608
<i>European Union, Asia, Australia, South America</i>	609

VOLUME 3

CONTACT REPORTS	610
PRIMARY PRODUCERS (CRUDE OIL EXTRACTORS)	610
<i>Company X</i>	610
SECONDARY PROCESSORS (REFINED OIL PRODUCERS).....	610
<i>24 companies</i>	
TERTIARY PROCESSORS (ENCAPSULATORS AND MICROENCAPSULATORS)	676
<i>9 companies</i>	
DISTRIBUTORS / RESELLERS.....	694
<i>8 companies</i>	
TRADERS.....	704
<i>2 companies</i>	
FOOD COMPANY END USERS	705
<i>14 companies</i>	
SUPPLEMENT COMPANY (BRAND HOLDER) END USERS	724
<i>2 companies</i>	
PHARMACEUTICAL COMPANY END USERS.....	727
<i>2 companies</i>	
FOOD PRODUCT DEVELOPMENT SERVICES	729
<i>4 companies</i>	
EQUIPMENT MANUFACTURERS	731
<i>Company Y</i>	731
OTHERS.....	732
<i>11 companies</i>	
ADDITIONAL CONTACTS FOR REFERENCE	760
MANUFACTURERS	760
<i>11 companies</i>	
END USERS	763
<i>7 companies</i>	
NEWS	766
OVERVIEW	766

<i>Health Benefits</i>	766
<i>Markets and Products</i>	766
<i>Competition</i>	769
<i>Labelling, Safety and Regulations</i>	771
RECENT NEWS ARTICLES	772
<i>80 articles</i>	

APPENDICES

COMPANY INFORMATION

18 companies

FOOD PRODUCT DEVELOPMENT SERVICES

*Leatherhead Food RA**Leatherhead Food RA Shelf Life Services**Reading Scientific Services**Sensory Dimensions*

FOOD PRODUCT LAUNCHES

*Fish Omega-3**Marine Omega-3**Omega-3 with claim*

OTHER PRESENTATIONS

*GOED**Molecular Distillation of Oil Refining*

REGULATION

*Article 13 Claims**Derogation of hygiene regulations**European Pharmacopoeia Fish Oil**European Pharmacopoeia Fish Oil Test method**Hygiene Regulations**Labelling Guidelines**USA Regulation of Dietary Supplements***TABLES**

TABLE 1	CPL ESTIMATE OF EXPECTED AND RAPID WORLD INGREDIENT SALES VALUE (\$M), VOLUME AND % GROWTH RATES	9
TABLE 2	CPL PRODUCT PRICES SUMMARY.....	10
TABLE 3	CPL ESTIMATE OF EXPECTED AND RAPID WORLD INGREDIENT SALES VALUE (\$M), VOLUME AND % GROWTH RATES	24
TABLE 4	PUFA MARKET DRIVERS	26
TABLE 5	MARINE OIL MARKET DRIVERS	27
TABLE 6	PUFA MARKET CHALLENGES	28
TABLE 7	MARINE OIL MARKET CHALLENGES	28
TABLE 8	CPL ESTIMATE OF INGREDIENT SALES VALUE (\$M) AND % GROWTH RATES	29
TABLE 9	CPL ESTIMATE OF INGREDIENT SALES VOLUME (KT) AND % GROWTH RATES	30
TABLE 10	WORLD INGREDIENT SALES VALUE (\$M) AND % GROWTH RATES	31
TABLE 11	EUROPEAN INGREDIENT SALES VALUE (\$M) AND % GROWTH RATES	33
TABLE 12	OTHER INGREDIENT SALES VALUES OBTAINED (\$M)	33
TABLE 13	US INGREDIENT SALES VALUE (\$M) AND % GROWTH RATES	34
TABLE 14	CONCENTRATES SALES VALUE (\$M) AND % GROWTH RATES	35
TABLE 15	INGREDIENT SALES VOLUME (KT) AND % GROWTH RATES	36
TABLE 16	CONCENTRATE SALES VOLUME (KT) AND % GROWTH RATES.....	38
TABLE 17	WORLD FISH OIL VOLUME (KT) USED FOR HUMANS	39
TABLE 18	CPL PRODUCT PRICES SUMMARY.....	40
TABLE 19	PRICE COMPARISON PRODUCTS	42
TABLE 20	PRICES BY PRODUCT TYPE	44
TABLE 21	MANUFACTURERS' PRODUCTS LISTING.....	80
TABLE 22	COMPANY X'S KEY PRODUCT RANGES	135
TABLE 23	COMPANY X'S PRODUCTS	136
TABLE 24	COMPARISON OF COMPANY Y'S PRODUCT WITH SPECIFICATIONS OF THE SOURCE MATERIAL...	147
TABLE 25	OMEGA PROTEIN STORAGE FACILITIES	183
TABLE 26	OMEGA PROTEIN HARVESTING AND PRODUCTION	190

TABLE 27	OMEGA PROTEIN REVENUES BY PRODUCT	190
TABLE 28	OMEGA PROTEIN INVENTORY	192
TABLE 29	COMPANY Z - PROFILE	192
TABLE 30	ONC DIETARY SUPPLEMENT PRODUCTS AND BRANDING IN CANADA	195
TABLE 31	ONC DIETARY SUPPLEMENT PRODUCTS AND BRANDING IN THE US	195
TABLE 32	ONC OTHER DIETARY SUPPLEMENT PRODUCTS AND BRANDING.....	197
TABLE 33	ONC FOOD INGREDIENT PRODUCTS AND BRANDING IN CANADA.....	197
TABLE 34	ONC FOOD INGREDIENT PRODUCTS AND BRANDING IN THE US.....	198
TABLE 35	ONC OTHER FOOD INGREDIENT PRODUCTS AND BRANDING	199
TABLE 36	COMPANY A'S DISTRIBUTION AGREEMENTS WORLDWIDE	207
TABLE 37	MANUFACTURERS CITING PRODUCT QUALITIES AND PROCESSING CLAIMS IN B2B MARKETING	236
TABLE 38	MANUFACTURER'S CITING ACCREDITATION, CERTIFICATION, HEALTH AND SAFETY IN B2B MARKETING	253
TABLE 39	LOCATION, TYPE AND SIZE OF FACILITIES	261
TABLE 40	US OMEGA-3 FISH OIL SUPPLEMENT MANUFACTURERS	272
TABLE 41	PRODUCT CLAIMS ABOUT THE FISH OILS IN DIETARY SUPPLEMENTS	325
TABLE 42	PRODUCT CLAIMS ABOUT THE FISH OIL INGREDIENTS IN FOOD PRODUCTS	329
TABLE 43	FOOD PRODUCTS WITH FISH OIL / OMEGA-3 CLAIM	336
TABLE 44	PHARMACEUTICAL PATENTS MENTIONING OMEGA-3	413
TABLE 45	GLOBAL PHARMACEUTICAL MARKET, \$B	477
TABLE 46	MARKET CONSOLIDATION IN THE GLOBAL PHARMACEUTICAL INDUSTRY	490
TABLE 47	THE EU PHARMACEUTICAL INDUSTRY IN FIGURES	508
TABLE 48	RESEARCH AND DEVELOPMENT IN THE EU PHARMACEUTICAL INDUSTRY	508
TABLE 49	THE PHARMACEUTICAL MARKET IN EUROPE, €B	509
TABLE 50	THE GERMAN PHARMACEUTICAL BASIC SUBSTANCES MARKET, €B	512
TABLE 51	MARKET SIZE OF THE ITALIAN PHARMACEUTICAL MARKET \$M	526
TABLE 52	ITALIAN IMPORT AND EXPORT OF PHARMACEUTICALS	527
TABLE 53	MARKET SIZE FOR THE BRAZILIAN PHARMACEUTICAL INDUSTRY, \$M	536
TABLE 54	MARKET SIZE FOR THE CHILEAN PHARMACEUTICAL INDUSTRY, \$M	537
TABLE 55	MAJOR GLOBAL FISH OIL REFINERS.....	636
TABLE 56	EUROPEAN OMEGA-3 FISH OIL MARKET VOLUME, VALUE AND UNIT COST	638
TABLE 57	% EUROPEAN MARKET VALUE AND VOLUME BY FISH OIL TYPE	638
TABLE 58	US OMEGA-3 FISH OIL MARKET VOLUME, VALUE AND UNIT COST	638
TABLE 59	% US MARKET VALUE AND VOLUME BY FISH OIL TYPE	638
TABLE 60	TOTAL US AND EUROPEAN FISH OIL MARKET VOLUME, VALUE AND UNIT COST	639
TABLE 61	% TOTAL US AND EUROPE MARKET VALUE AND VOLUME BY FISH OIL TYPE	639
TABLE 62	RETAIL VALUE OF O3 PRODUCTS BY COUNTRY AND SECTOR	640
TABLE 63	% RETAIL VALUE OF O-3 PRODUCTS BY COUNTRY AND SECTOR	640
TABLE 64	SPECIFICATIONS OF 18:12 OIL REQUIRED BY COMPANY Y.....	680
TABLE 65	SOURCE & TECHNOLOGY FOR NUTRITIONAL OILS	685
TABLE 66	MARKET FOR NUTRITIONAL OILS	685
TABLE 67	EPA/DHA OMEGA-3 RETAIL AND INGREDIENT SALES (US\$M).....	743
TABLE 68	GLOBAL OMEGA-3 MARINE OIL MARKET: VOLUME, VALUE AND GROWTH	753
TABLE 69	GLOBAL OMEGA-3 MARINE OIL MARKET VOLUMES.....	754

FIGURES

FIGURE 1	PRODUCT FORMS AND FORMATS	100
FIGURE 2	DISTRIBUTION OF PRODUCTS BY PERCENTAGE OF OMEGA-3	101
FIGURE 3	FREQUENCY OF MANUFACTURERS CITING PRODUCT QUALITIES IN THEIR ADVERTISING	251
FIGURE 4	FREQUENCY OF MANUFACTURERS CITING PROCESS CLAIMS IN THEIR ADVERTISING.....	252
FIGURE 5	FREQUENCY OF MANUFACTURERS CITING ACCREDITATIONS IN THEIR ADVERTISING.....	260
FIGURE 6	SUPPLEMENTS SUPPLY CHAIN	271
FIGURE 7	OMEGA-3 PRODUCT LAUNCHES WORLDWIDE	337
FIGURE 8	OMEGA-3 PRODUCT LAUNCHES IN EUROPE	338
FIGURE 9	OMEGA-3 PRODUCT LIFE CYCLE	338
FIGURE 10	PRODUCTION OF THE API FOR OMEGA 3 PHARMACEUTICAL PRODUCT.....	370
FIGURE 11	COST OF DEVELOPING A NEW MEDICINE	482
FIGURE 12	DEVELOPMENT OF A DRUG FROM TARGET IDENTIFICATION TO POST-LAUNCH PRODUCT REVIEW ..	485
FIGURE 13	NEW MOLECULAR ENTITIES APPROVED IN THE US.....	485

FIGURE 14 SUCCESS RATES IN DRUG DEVELOPMENT 487

FIGURE 15 PERCENTAGE MARKET SHARE FOR PRODUCTS LAUNCHED IN THE LAST FIVE YEARS 489

FIGURE 16 PHARMACEUTICAL INDUSTRY EXPENDITURE IN R&D IN EUROPE 509

FIGURE 17 SPLIT OF EUROPEAN PHARMACEUTICAL MARKET 510

FIGURE 18 FUNDING OF HEALTH-RELATED R&D IN THE UK 517

FIGURE 19 COMPARISON OF SHARE OF GLOBAL PHARMACEUTICAL R&D INVESTMENT 517