STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

MEETING HELD AT

Palmer House Hilton
Chicago, IL

Tuesday, August 27, 2013

REPORT OF THE EXPERT REVIEW PANEL (ERP) PROCEEDINGS

Expert Review Panel Member Attendees:

Darryl Sullivan, Chair, *Covance Laboratories*
John Austad, *Covance Laboratories*
Sneh Bhandari, *Silliker Laboratories*
Esther Campos-Giménez/Adrienne McMahon, *Nestlé/Wyeth*
Scott Christiansen, *Perrigo Nutritionals*
Jonathan DeVries, *Medallion Labs/Gen. Mills*
Don Gilliland/Karen Schimpf, *Abbott Nutrition*
Min Huang, *Aegis Corp.*
Harvey Indyk/Brendon Gill, *Fonterra*
Estela Kneeteman, *INTI*
Bill Mindak, *FDA*
Shay Phillips, *Mead-Johnson Nutritional*
Melissa Phillips/Kate Rimmer, *NIST*
Jinchuan Yang, *Waters Corp.*

AOAC Staff including:

Delia Boyd
E. James Bradford
Scott Coates
Dawn Frazier
Deborah McKenzie
Alicia Meiklejohn
Anita Mishra

Expert Review Panel Members Not in Attendance:

Jeanne Rader, *FDA*
Günther Raffler, *Danone*

I. WELCOME/INTRODUCTIONS

Darryl Sullivan (Covance), Chair of the Stakeholder Panel on Infant Formula and Adult Nutrition, introduced and welcomed the participants to Expert Review Panel (ERP) meeting of the SPIFAN project. The ERP members in attendance and participants were introduced.

II. DOWN SELECTION PROCESS & REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP)

The Expert Review Panel (ERP) discussed the methods and selected a single method for multi-lab testing (MLT) through the SPIFAN process. The following is the result of the discussions and vote.

1) Vitamin C

a. OMA# 2012.21 (VitC-02) & OMA# 2012.22 (VitC-03)
b. **Score**: 757 points (OMA# 2012.21) / 826 points (OMA# 2012.22)

2) Choline

a. OMA# 2012.18 (Chol-03) & OMA# 2012.20 (Chol-07)
b. **Score**: 852 points (OMA# 2012.18) / 869 points (OMA# 2012.20)

3) Iodine

a. OMA# 2012.14 (Iod-01) & OMA#2012.15 (Iod-02)
b. **Score**: 838 points (OMA# 2012.14) / 877 points (OMA# 2012.15)

4) Pantothenic Acid

a. OMA# 2012.16 (Panto-01) - **Moved to MLT**

5) Carnitine

a. OMA# 2012.17 (Carn-01) - **Method Withdrawn**

1. Move to advance the selected method for reproducibility study

Method	Method Title	Reviewer(s)	Score	Vote	Comments
VitC-02	*2012.21 - Determination of Vitamin C by HPLC with UV Detection*	Brendon Gill John Austad	757		✦ No measurable bias against the SRM ✦ Met all SMPR requirements ✦ SRM results; average was higher ✦ Which option was used for data collection?
VitC-03	*2012.22 - HPLC-UV Determination of Total Vitamin C in a Wide Range of Fortified Food Products*	Jon DeVries Harvey Indyk	826	Yes- 11/ No-0 /Abstain-2	
Chol-03	*2012.18 - Simultaneous Determination of Free Carnitine and Total Choline by Liquid Chromatography/Mass Spectrometry in Infant Formula and Health-Care Products: Single-Laboratory Validation*	John Austad Sneh Bhandari	852		✦ Within RSD requirements ✦ Meets SMPR
Chol-06	*2012.19 - Method Development for Determination of Total and Free Choline in Nutritional Products by LC–MS/MS*	Method withdrawn			
Chol-07	*2012.20 - Determination of Choline in Powdered Infant Formula*	Scott Christiansen Shay Phillips	869	Yes- 12/ No-0 /Abstain-2	✦ Repeatability o Pretty rugged ✦ Meets SMPR ✦ Instruction o When predicted life time ✦ Use of guard column should be part of system suitability
Iod-01	*2012.14 - Determination of Total Iodine in Infant Formula and Nutritional Products by Inductively Coupled Plasma/Mass Spectrometry: Single Laboratory Validation*	Bill Mindak Min Huang	838		✦ Well written method ✦ Difference in the sample prep ✦ digestion
Iod-02	*2012.15 - Method of Analysis for the Determination of Total Iodine in Foods and Dietary Supplements Using Inductively Coupled Plasma-Mass Spectrometry*	Esther Campos-Giménez Min Huang	877	Yes- 12/ No-0 /Abstain-2	✦ May require additional detail ✦ Decide on one (1) digestion technique only ✦ See data on both through MLT
Panto-01	*2012.16 - Pantothenic Acid (Vitamin B5) in Fortified Foods: Comparison of a Novel Ultra-Performance Liquid Chromatography-Tandem Mass Spectrometry Method and a Microbiological Assay (AOAC*	John Austad Don Gilliland		Yes- 13/ No-0 /Abstain-1	✦ Units were wrong o Units in grams should be milligrams ✦ Address high fat issue ✦ Use free pantothenic acid according to NIST ✦ Define what the prep looks

	Official MethodSM 992.07)				like o No option (one or the other)
Carn-01	*2012.17 - Single-Laboratory Validation of a Liquid Chromatographic/Tandem Mass Spectrometric Method for the Determination of Free and Total Carnitine in Infant Formula and Raw Ingredients*	Method withdrawn			

III. REVIEW OF METHODS BY EXPERT REVIEW PANEL (ERP) FOR FIRST ACTION *OFFICIAL METHOD*^{SM} STATUS

The Expert Review Panel (ERP) members Primary and Secondary Reviewers provided updates on their assigned method(s) and rendered a decision on First Action *Official Method* status. The ERP collectively discussed the method(s) and selected a single method to move forward through the SPIFAN process.

1. **Folate**
   a. **Fol-20**
   b. **Fol-21**

2. **<u>Move to advance the selected method for First Action *Official Method*^{SM} Status</u>**

Method	Method Title	Reviewer(s)	ERP Vote	Reviewer's Comments
Fol-20	*A validated method to determine folic acid and 5-methyl THF in adult/infant nutritional formulae using ultra performance liquid chromatography-tandem mass spectrometry*	Adrienne McMahon Melissa Phillips/Kate Rimmer	Yes- 3/ No-5/Abstain-2	➢ Recovery didn't meet the SMPR ➢ Extraction o Difference in the totals ➢ Values in the SRM is high
<u>ERP RECOMMENDATIONS FOR FOL-20:</u> ➢ More data on SPIFAN suite o Choose between heat treatment or o Tri-enzyme ➢ Check calculations *Will not move to MLT at this time **Study director proposes to have additional data within one month				
Fol-21	*Single-Laboratory Validation - Free Folates in Infant Formula and Adult/ Pediatric Nutritional Formula by UHPLC-UV*	Min Huang Shay Phillips	Yes- 10/ No-1/Abstain-1 **Second vote:** Yes- 10/ No-0 /Abstain-2	➢ Meets SMPR ➢ Sample prep ➢ Standard purity
<u>ERP RECOMMENDATIONS FOR FOL-21:</u> ➢ Check methodology (concentration of calibration standard) ➢ Use spectro-photometric combined with HPLC (recommend both) ➢ MS/MS not UV ➢ Tri-enzyme Caveat ➢ Measurement of poly-glutamate				

IV. UPDATE ON MULTI-LABORATORY TESTING SCHEDULE

Robert Rankin (International Formula Council) provided an update on the Multi-Laboratory Testing schedule.

V. UPDATE ON VITAMIN A & E

Adrienne McMahon of Wyeth Nutrition (formerly Pfizer) provided an update on the Vitamin A & E method slated to move to multi-lab testing.

Method	Method Title	Original Reviewer(s)	Vote	Recommendation
VitA-17 **VitE-19**	*2012.10 - Simultaneous Determination of Vitamins A, E and Beta Carotene/Mixed Carotenoids in Infant Formula by Normal Phase HPLC. Submitted by Pfizer Nutrition.*	Erik Konings Kathy Sharpless/ Kate Rimmer	Yes- 12/ No-0 /Abstain-1	➢ Move to MLT

VI. REVIEW ACTIONS FROM PREVIOUS MEETINGS

Darryl Sullivan & Anita Mishra reviewed previous actions/items from past meetings.