**Minutes**

**HL7 Structured Product Labeling for Food and Dietary Supplements**

**April 25, 2016**

**Attendees:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Present** | **Name** | **Organization** | **E-mail** |
|  | Andrews, Karen | USDA | Karen.Andrews@ars.usda.gov |
| X | Ayres, Elaine | NIH | eayres@nih.gov |
|  | Brown, Scott | GS1 | Scott.Brown@gs1us.org |
| X | Brockmire, Lauren | FDA |  |
|  | Brunone, Theresa | GSK | theresa.m.brunone@gsk.com |
| X | Dittloff, Margaret | CBORD | mkd@CBORD.com |
| X | Dwyer, Johanna | NIH | dwyerj1@od.nih.gov |
|  | Haytowitz, David | USDA | David.Haytowitz@ars.usda.gov |
| X | Heintz, Kasey | FDA | kasey.heintz@fda.hhs.gov |
|  | Helton, Edward | NIH | heltone2@mail.nih.gov |
|  | Hoggle, Lindsey | AND | LHoggle@eatright.org |
| X | Kretser, Alison | ILSI | akretser@ilsi.org |
| X | Leftwich, Russell | AAAAI | rleft@pobox.com |
| X | Page, Tammy | FDA - CFSAN |  |
| X | Pehrsson, Pamela | USDA | Pamela.Pehrsson@ARS.USDA.GOV |
|  | Perkins,Vada | FDA | Vada.Perkins@fda.hhs.gov |
| X | Saldanha, Leila | NIH | saldanhl@mail.nih.gov |
| X | Schmit, Diane | FDA | Diane.Schmit@fda.hhs.gov |
| X | Venter, Carina | AAAAI | Carina.Venter@cchmc.org |
|  | Young, Michael | AAAAI | Michael.Young@childrens.harvard.edu |
|  |  |  |  |

**Conference Call Information:**

Phone Number: +1 770-657-9270  
Participant Passcode: 7485962

**Web Meeting Info (does not include audio connection)**

[**http://www.webex.com**](http://www.webex.com)

Meeting ID 193 128 608 (no password).

Direct Meeting Link: <https://meetings.webex.com/collabs/#/meetings/detail?uuid=M8B9ZKDZAIIKHBGUAR299G14AE-4MOF&rnd=548277.12942>

**Project Wiki:** <http://wiki.hl7.org/index.php?title=Structured_Product_Labeling_for_Food_and_Dietary_Supplements_(SPLr8)>

**AGENDA:**

1. Review and approval of March 28 minutes
2. Specific reviews of the requirements spreadsheet
   1. Office of Dietary Supplements (ODS)
   2. AAAAI Subgroup
   3. FDA Subgroup
3. Minutes: March 28: Move to approve: Russ/Johanna Abstentions - 0 , Negatives - 0 , Approved - 9
4. Office of Dietary Supplements comments
   1. The Office of Dietary Supplements at the NIH reviewed the requirements documents first with Elaine Ayres, and then with Constance Hardy from FDA CFSAN. Written comments were provided back to Elaine Ayres and will be incorporated into the final requirements. It was noted that nutrients in dietary supplements are treated differently than in foods.
5. AAAAI Subgroup
   1. The AAAAI sub-group led by Carina Venter has developed a list of foods known to cause adverse reactions including IgE based food allergies, Food Protein-Induced Enterocolitis Syndrome (FPIES) and Eiosinophilic Esophagitis (EOE). In addition to the eight specified foods as per labeling regulations, the group created expanded lists of specific foods for tree nuts, crustacea shellfish, bony fish and mollusk shellfish. Additional foods included on food labels from other countries were also added to the list – for example sesame, mustard, celery and lupine. The group requests that these specific foods when included in a food product be specifically included as allergens within the electronic labeling file.
   2. Carina will provide a final list of foods to Elaine.
6. FDA
   1. History of SPL at CFSAN for Food and Dietary Supplements. The standard has not been pursued because there is no regulatory mandate.
   2. Pilot study done several years back to create sample SPL files for food. It showed that the current SPL r7 standard contains most if not all of the requirements for conveying food label information.
   3. A draft implementation guide was also produced. It was noted that LanguaL was used as a means of categorizing foods. Kasey will pursue why these was included as a requirement.
7. Next steps
   1. Elaine will finalize the requirements and send to the FDA for a comparison against the current SPL standard.
   2. The group will be kept informed about the current state of the requirements.
   3. A pilot between NIH and FDA will be pursued to test the standard using dietary supplements.