

Summary
Joint Standardized Information on Dietary Ingredients (SIDI™) Working Group
In-person Meeting

August 6, 2009, 8:00 am – 3:30 pm EDT
 CHPA Board Room
 900 19th Street, NW, Suite 700
 Washington, DC 20006
 202-429-9260

| Companies | | Organizations |
|----------------------|------------------------|----------------------|
| Albion | Embria Health Sciences | AHPA |
| A.M. Todd | GNC | CHPA |
| BASF | Joy QM Systems | CRN |
| Bayer | Kemin | NPA |
| Beijing Ginkgo Group | Kyowa Hakko | FDA |
| Colorcon | NBTY | NSF |
| DSM | Nutramax | USP |
| EAS Consulting Group | Nutrilite | |

Introduction:

Andrew Shao (CRN) opened the meeting with a suggestion to establish a core SIDI Working Group that will be actively involved going forward in the projects associated with ingredient supplier qualification. The projects would be of interest to members in the regulatory/quality area, although others, including marketing experts would be of great value to the Working Group in spreading awareness. Current SIDI WG members may choose to continue participation and/or nominate others within their companies/organizations to the WG as appropriate. Those companies who are not currently members of the SIDI WG but are interested in participating via their respective associations should contact their association representatives.

Andrew briefly reminded WG members that the group’s efforts in creating a voluntary industry-wide ingredient supplier qualification program help the dietary industry get ahead of regulation i.e., Food Safety legislation slated for the current Congress. In the last meeting, there was a consensus in favor of this proactive approach. There is precedence set by other industries e.g., the excipients industry, that have met with similar challenges and have developed

programs to address them. There are existing guidelines and tools that could serve as the template or framework for the dietary supplement industry versions. Andrew emphasized that industry feedback on the usefulness of guidelines/tools is essential for the trade associations to gauge and justify the time and resources needed for establishing dietary supplement – specific guidelines.

The minutes of the June 24th Workshop were reviewed. At that time, Food Safety was not a priority for Congress which was preoccupied by Health care Reform. There is no doubt, however, that the pending Food Safety bill would address in detail supply chain management and traceability. It follows that proper supplier qualification is necessary. Although the dietary supplement GMPs mentioned supplier qualification, it did not offer specifics on how ingredient suppliers are to be qualified. Hence, it would behoove industry to be prepared by initiating its own guidelines and programs. The meeting attendees heard from Bill Frankos (FDA) that the FDA expects industry to be innovative in ensuring safety and quality of ingredients and that supplier qualification goes beyond questionnaires. At the previous meeting, attendees were presented with manufacturer and supplier perspectives on ingredient supplier qualification, a case for industry-sponsored audit program i.e., one developed by IPEC for excipients, and benefits and drawbacks of such a program for the DS industry. Also, Paul Bolar (Pharmavite) offered a pyramid or step-wise approach towards establishing a full blown ingredient supplier qualification program starting with the foundation of SIDI, and building with guidelines such as Certificate of Analysis guideline, Dietary Ingredient GMP guideline, CofA Verification guideline, and Dietary Ingredient Supplier GMP Audit guideline.

Define objectives and prioritize projects:

At the present meeting, the WG members discussed whether it would take the step-wise approach or one in which guidelines are developed in parallel. The parallel approach would save time considering inspections for mid size companies have started, but may prove overwhelming. Most agreed that a “pyramid” approach would be more feasible and tactically effective. Since the industry participation is voluntary, a strong foundation of straight forward and easily acceptable guidelines is needed before presenting industry with more complicated and potentially contentious guidelines/tools. For example, a CofA guideline could be developed quickest and may easily garner acceptance by

industry. The best case scenario that could be imagined would be for the guidelines to shift from voluntary status to “mandatory” as they become industry practice, prove useful and receive a tacit endorsement by regulators. Moreover, small to mid-size companies, which often lack the infrastructure for proper ingredient supplier qualification, might be more open to incorporating these guidelines into their systems.

Some discussion points include:

- FDA should ask about supplier qualification during inspections and communicate what level of information is needed beyond questionnaires. Even though Bill Frankos has said SIDI provides the kind of information FDA wants to know, this message needs to be reverberated when the Agency conducts inspections whenever possible.
- SIDI lacks overwhelming success with manufacturers; some are not even aware of SIDI. Manufacturers need to communicate with suppliers about what information is acceptable (SIDI); they could educate those suppliers not aware of SIDI. Some suppliers find it difficult to tell their customers what to accept, so the demand for SIDI needs to come from the manufacturers.
- Companies’ internal communication is insufficient and the complexities of proper ingredients supplier qualification has not trickled down to sales/purchasing people who are directly involved making decisions about the source of ingredients.
- It was suggested that trade associations send SIDI to all industry members to increase awareness of the protocol.
- Considerations for a step-wise process: time-consuming and may lose emphasis; need to set time frames and metrics to keep in mind the final goal while developing guidelines somewhat in isolation.
- Guidelines need to incorporate both manufacturer and supplier perspectives, and have international relevance and support from regulators.

Next, project prioritization and timelines were discussed. The first project the WG determined to begin working on is the development guidelines/tools. After consideration of which guidelines are most feasible (defined, smaller scope) and immediately critical, the WG determined that it would form two subcommittees

that will begin developing three guidelines simultaneously. The Certificate of Analysis and CofA Verification guidelines are related and would be completed first, followed by the Dietary supplement component GMP (suggested name change for “Dietary ingredient GMP” to encompass non-active components) guideline. The Dietary supplement component supplier audit guideline would be contingent upon the Dietary supplement component GMP guideline and would be completed last.

Bradley Williams (FDA) shared that the list of guidelines/tools is comprehensive, but could include a small-entity compliance guideline (which FDA is currently working on). Dan Fabricant (NPA) suggested the addition of a self-assessment audit checklist which could be used by manufacturers to evaluate their internal processes as well as their suppliers. This checklist was later determined to be a first step to the Dietary supplement component GMP guideline.

The larger, long-term project---development of a voluntary industry-sponsored ingredient supplier qualification program---has yet to be discussed fully by the WG. However some key considerations were raised:

- 1) What goes into the checklist/outline addressing the elements manufacturers need to examine in qualifying ingredient suppliers? This is likely the first step in the industry-sponsored qualification program.
- 2) Should this program be a shared audit program or a certification program? The shared audit program takes is possibly easier and takes less time to develop and may adequately address the immediate need for qualification. Points to consider for a shared audit program include degree of industry buy-in, GMA third party audit program as a model and process of handling “negative” audit reports. The certification program is likely a longer term endpoint that would need standards and a system of accreditation of third party certifiers.

A third subcommittee was formed to lead outreach/communication efforts. An outline of projects, timelines and subcommittee designations were constructed. The last portion of the meeting was devoted to reviewing the Certificate of Analysis guideline for excipients, which will serve as a template for the dietary ingredient version. The group’s suggested edits were captured by tracked changes to the document (to be provided as an attachment).

Outline of Projects

Project objective/scope:

<To Be Added or Revised>

- Guidelines/tools (listed by priority rank):
 1. Certificate of Analysis – Sub-committee #1
 - Guideline
 - Verification Guideline
 - Tentative completion date: no later than October 2009 (approval by SIDI WG) - *may be revised based on sub-committee assessment*
 2. Dietary supplement component GMP guideline – Sub-committee #2 [first task]
 - Self-assessment audit checklist (dual purpose use: Manufacturers and Suppliers, possibly Retailers)
 - Tentative completion date: proposed for January 2010 (draft #1 – approved by SIDI WG) - *may be revised based on sub-committee assessment*
 - Starting point: (Food GMPs + elements of DS GMPs as appropriate; CRN GMPs comparison table; NPA audit checklist)
 - Sub-committee #2 (first task) will need to work aggressively and meet frequently to meet target date.
 3. Dietary supplement component supplier GMP audit guideline – Sub-committee #2 [second task]
 - Tentative completion date: proposed for March 2010 (draft #1 – approved by SIDI WG) - *may be revised based on sub-committee assessment*
- Timeline Considerations
 1. Number of meetings/teleconferences/webcasts/email
 - Resource to arrange t-cons: www.doodle.com;
www.setameeting.com
 - Webex for webinars (CHPA/member companies)
 2. Frequency of interactions

3. Full SIDI working group/smaller SIDI working teams or subcommittees/association staff /combination or other permutation????
4. Executive Committee approval

Sub-committee #1

Mike Chansilp, NBTY
Elinor Hitchner, Bayer
Jay Lee, Beijing Ginkgo Group
Anthony Palmieri, DSM (tentative chair)
Patricia Rohr, Albion
Alexa Smith, Colorcon
Andrew Shao, CRN/association rep (liaison)
Devon Powell, AHPA/association rep
Regular meeting day & time: TBD

Sub-committee #2

Kristen Blanchard, Nutramax (second task)
Kevin Boot, Embria
Mike Chanslip, NBTY (tentative)
Marvin Herr, Bayer
Joy Joseph, Joy Quality Management Systems
Kazutoshi Kuroda, Kyowa Hakko
Dave Schoneker, Colorcon
Ed Steele, EAS Consultant (second task)
Ranga Velagaleti, BASF
Ed Wyszumiala, NSF (tentative chair)
Dan Fabricant, NPA/association rep (liaison)
Andrew Shao, CRN/secondary association rep
Devon Powell, AHPA/third association rep
Regular meeting day & time: TBD

Sub-committee #3 – Outreach/Communication

Todd Norton, AM Todd
Anthony Palmieri, DSM
Karen Todd, Kyowa Hakko (tentative chair)
Marcia Howard, CHPA/association rep (liaison)

Devon Powell, AHPA/association rep

- Draft budget proposals
- Proposals for tradeshow outreach, other venues/forums
- Develop promotional kit that can be used by WG members and others
- Webinar outreach

Regular meeting day & time: TBD

Subcommittee Action Items from the Meeting:

- 1) Trade associations send SIDI Protocol to membership and other contacts in the industry.
- 2) CRN to share the GMP Comparison table and Dan Fabricant share NPA's self-assessment audit checklist with Subcommittee #2 (send to chair first).
- 3) Marcia Howard and Devon Powell inform the WG about the availability of a shared document system within next 2-3 weeks.
- 4) Subcommittee chairs determine the date of the first meeting for their respective subcommittees within the next 2 weeks and set up a regular meeting schedule. The Association representatives will send email lists for each subcommittee.
- 5) Trade associations or WG members recruit an herbal/natural product manufacturer to participate in the CofA guideline subcommittee (#1).