Developing a Dietary Supplement Product Registry

Council for Responsible Nutrition

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Dietary Supplement Marketers are in the Healthcare Business

"People purchase [dietary supplements] with the expectation that they will help keep them healthy…. Every time a consumer opens a bottle, pouch or blister pack and puts one of our products in their mouth, we take our place as a provider of healthcare…"

S. Mister. "Seriously, what business are you in?" ***NBJ, The Dark Issue***, 2016.

Everyone is watching…

- Increased visibility at FDA
- Heightened scrutiny from the Justice Dept.
- Ongoing concerns from Senators Durbin & Blumenthal
- New inquiries from state attorneys general
- Continued concern from state legislatures
- Regular “drumbeat” for new regulation from industry critics
- Nearly constant negative attention from consumer media

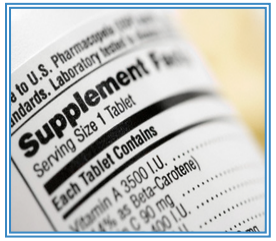
What we need to do about it…

- Address accountability – Dietary Supplement Product Registry
- Address ingredient integrity – Raw Material Quality Guidelines
- Address GMP compliance – Common measuring stick for assessing compliance with GMP regulations
- Urge for More Deterrence – Increased enforcement from FDA, DoJ and FTC for egregious violations

DS REGISTRY: What are we trying to do?

Objective: To create an industry-initiated and administered searchable database of dietary supplements that provides basic required information about finished products and permits expandable fields for companies to voluntarily provide additional information about the product, its ingredients, its supply chain and its manufacturing.

WHY create a product registry?



- To demonstrate pro-active self-regulation by industry;
- To strengthen the industry's relationship with the FDA, by providing FDA with relevant information about DS and improve its ability to obtain product, ingredient and manufacturer information;
- To counter the belief (perpetuated by FDA itself) that the agency does not know, and cannot determine, the size and breadth of the industry—so we will change the landscape;
- To assist retailers to more easily evaluate dietary supplements and select quality products for their customers;
- Ultimately, to allow consumers to identify, evaluate and compare dietary supplements based on labeling, contents and indicia of quality, to more wisely "navigate the aisle";
- To improve retailers', regulators' and elected officials' perception of the industry by demonstrating increased transparency; and
- To establish an industry-run, voluntary registry that might serve as a model for a mandatory program in the future.

Proposed Dietary Supplement Product Registry

Tier #1

- No cost to industry
- Consists of **public facing** and **FDA facing** fields – free
- Data to be provided by brand owner – user friendly process
- Tier #2 users can opt-in to show additional info
- Will interface with ODS label database

Tier #2

- Fee based program
- Data entry to be handled by the product registry administrator
- Data access/visibility controlled by manufacturer/marketer who supplies information
- Additional features generated by the system (data mining and analytics) can be accessed by industry

Tier #1 Open Access

Public facing tier similar to current ODS DSLD

Modeled from Product Transparency WG Framework

- Unique product identifier
- Product brand name
- Dosage form
- Supplement Facts label information (dietary ingredients and quantity)
- Other label statements (label claims)
- Contact information provided on the label
- Copy of product label
- Certification statements provided on the label
- Date entered into registry
- Availability (On/Off Market)

Tier #1

FDA Access

Confidential Tier #1 data: available to FDA only

- All information in basic access tier
- (a) Product manufacturer address, phone and email
- (b) Product packager address, phone and email
  - OR - 24/7 Contact information for Quality Assurance Executive in lieu of fields (a) and (b)
- Name, address, phone number and email address of person submitting the notification

- *Structure/Function claim notification (submitted/not submitted/not applicable) and FDA response, if applicable. (Tier #2?)*

Tier #2

Tier #2 – opportunity to share additional quality practices/ attributes with stakeholders

(fee based)

All information in basic access tier

Additional data fields to be finalized by a CRN appointed task force

All data can be made available or invisible to specific user groups (FDA, general public and by permission)

Database will be iterative

Examples of proposed Tier #2 data:

- Finished product C of A, full disclosure of formula, test results and methods, audit information, raw material spec sheets, raw material CoAs, regulatory status of ingredients, etc.

Some final thoughts…

- Don’t let the perfect be the enemy of the good.
- We must do now what we have consensus to do now; we can go farther later.
- But we need to act: doing nothing squanders this opportunity.
- This requires compromise and some sacrifice–and a little discomfort. **Disruption always does**.