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VIA ELECTRONIC SUBMISSION

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Re: Notice of Opportunity for Public Comment on the Dietary Supplement Label Database. 80 Fed. Reg. 66549 (October 29, 2015). Document No. 2015-27625.

The Council for Responsible Nutrition (CRN)[1] respectfully submits the following comments to the Office of Dietary Supplements (ODS) at the National Institutes of Health on the Dietary Supplement Label Database (DSLD). CRN appreciates this opportunity to provide comments about additional features and functionality improvements that would make the DSLD a more useful tool for users.

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

Many CRN members currently submit product labels to the DSLD. CRN hopes that in the near future the DSLD can become a complete and authoritative repository of supplement labels that reflects all dietary supplement products sold in the United States. We understand that currently product labels are entered into the DSLD *via* voluntary submission of the label by the manufacturer or marketer of the product, or through an online search for product labels by the database administrator. Increasing voluntary participation in the DSLD by the dietary supplement industry will reduce the time and effort required by the database administrator to actively seek product labels for inclusion in the database and will improve the accuracy of the information in the DSLD.

In order to encourage greater industry participation in the DSLD, CRN members have identified several areas where the DSLD can be modified or improved to better serve stakeholders. CRN recognizes that the primary objective of the DSLD is to provide information on dietary supplement products to researchers; however, additional stakeholders including consumers, retailers, regulators, policy makers, and industry, could benefit from a more robust DSLD. Moreover, CRN developed a detailed framework for a voluntary product registry that aims to increase transparency about dietary supplement products (enclosed). CRN recognizes that the DSLD has the potential to serve as such a product registry as it already satisfies several of the voluntary product registry framework recommendations. We appreciate this opportunity to share recommendations to modify the DSLD so it can better serve a broader group of stakeholders. CRN's suggestions for modifications are explained in detail below.

Database Efficiencies

As mentioned, many CRN members actively participate in the DSLD by regularly submitting labels to the DSLD. Collectively, we recommend several improvements that would

increase the efficiency and functionality of the database and result in greater industry participation:

1) CRN notes that the current DSLD contains products that are not dietary supplements. We recommend that ODS add only labels of dietary supplement products in the DSLD and remove from the current database all products that are not dietary supplements, that is, products that (a) are not identified as a dietary supplement in their statement of identity per 21 CFR 101.3(g) and (b) do not bear a "Supplement Facts" label.

2) If the DSLD is to become the authoritative repository for all dietary supplement product labels, the database administrator would need to be able to process labels significantly faster than the recently reported rate of 1,000 labels per month. We recommend that ODS allocate more resources to processing labels and adding them to the DSLD.

3) There should be a pre-defined and consistent time-frame within which a product label becomes searchable in the database after information has been submitted by the product manufacturer or marketer. At present, there is no defined timing for product labels to appear in the DSLD after submission. We recommend that ODS clearly communicate and adhere to a time-frame for label upload to the DSLD to help manage the expectations of product label submitters. In addition, other users would be able to better gauge the current breadth and depth of the dietary supplement market when searching the DSLD.

4) CRN recommends that ODS develop a clear process to update labels and remove errors in the DSLD at the request of the manufacturer or marketer. The process should include defined timelines (e.g., updates and removal of errors are reflected in the DSLD within a reasonable number of days of receiving a request) to ensure that updates and error

removals are completed in a timely manner. In addition, the updated label should replace any previous and outdated labels for the same product, and the date of label update should be stated. The DSLD should also make previous product labels available via a link in the current product information and clearly identify previous labels as such. Further, product labels with erroneous information should be completely removed and replaced by the correct label at the request of the manufacturer or marketer.

5) CRN recommends that ODS delineate an efficient process for removing discontinued products from the "On Market" list of products in the DSLD. CRN members who actively participate in the DSLD indicate that the process of moving a product from "On Market DSLD" to the "Off Market DSLD" in the database needs to be more consistent and efficient. Moreover, CRN understands that discontinued products can be searched by using the "Advanced Search" function and selecting "Off Market DSLD." CRN recognizes that it is important for the DSLD to include archived information that allows researchers to access historic label information and agrees that discontinued products should be isolated into the "Off Market DSLD" category. We recommend that the DSLD continue to enable the "Advanced Search" function as the only method to search for discontinued products.

<u>Unique Product Identifier</u>

CRN recommends a more flexible unique product identifier system to replace the current DSLD record number. Unlike the current DSLD record number that is generated *after* a product label submission, CRN recommends that a unique product identifier be designed in a manner that allows companies to determine the product identifier *before* a product is submitted to the DSLD

and to voluntarily print the product identifier on their product labels if they so choose. For clarification, CRN is not suggesting that the unique product identifier be a mandatory element in the product label, as this would have to be specified in regulation. However, we believe many dietary supplement manufacturers and marketers would voluntarily print the identifier on product labels, which may aid in product identification and help improve DSLD accuracy. Furthermore, we recommend an additional field in the database to enable searching for a product by its unique product identifier so that products on the market could be more easily identified in the DSLD. CRN also recommends that the unique product identifier system should be distinct from other product category identification systems. This would help differentiate dietary supplements from other products, such as over-the-counter drugs, which have their own distinct identification systems.

The unique product identifier should be designed to: (a) identify the product as a dietary supplement; (b) identify the Responsible Party[2]; and (c) be unique to the individual product formulation (see enclosed framework for the definition of "unique product formulation"). We recommend that the unique product identifier consist of two numeric parts, preceded by a prefix to designate the product as a dietary supplement. We propose "DS" as the common prefix. The first numeric part would correspond to the Responsible Party identifier and would be assigned by the database administrator to the Responsible Party. The Responsible Party identifier would be the only numeric part that requires assignment by the database administrator. The Responsible Party identifier would be the first numeric part for all products marketed by the particular

[2] For the purposes of the ODS DSLD, the "Responsible Party" submits the dietary supplement product label for inclusion in the database. A firm may self-designate as the "Responsible Party" or assign a "Responsible Party" to submit the product labels on their behalf.

Responsible Party. For efficiency, CRN recommends that the database administrator develop an automated process to generate Responsible Party identifiers.

The second numeric part of the unique product identifier would be self-assigned by the Responsible Party and be unique to the specific product formulation associated with the submitted label. Once a Responsible Party obtains the first numeric part from the database administrator, it has the ability to self-generate the second numeric part, and this step can be worked into the product development pipeline. The self-generating function is important because it allows the Responsible Party to provide the unique product identifier as part of the information submitted for products entered into the DSLD, and allows the manufacturer or marketer to include the unique product identifier on the label if desired.

If a new unique product identifier system is adopted, there would be period to phase in the product identifier and phase out the DSLD record number. For products entered into the DSLD following adoption of the unique product identifier system, the unique product identifier would be included as part of the product information in the DSLD. For products already in the DSLD with only the DSLD record number, the Responsible Party could request the addition of a unique product identifier for each unique product formulation. In addition, CRN notes that the current DSLD contains a separate record for each package size of a dietary supplement product. CRN recommends that the DSLD treat each unique product formulation, regardless of package size, as a record with a unique product identifier and provide links within the product information to the labels of the various product package sizes. A benefit of this format is that searches can be specific to the unique product formulation and information on various package sizes can be provided without recreating multiple records for the same dietary supplement product where the only difference is the package size.

CRN recognizes that the development of a new product identifier system would require more resources from the DSLD database administrator; however, a unique product identifier system as described would greatly augment the utility of the DSLD for a variety of stakeholders.

Confidential Data Accessible to Only FDA

Although the purpose of the DSLD is to serve research functions, CRN recognizes the potential use of the DSLD by FDA as a regulatory tool. The DSLD already allows stakeholders to identify what dietary supplements are on the market, the identity and levels of each ingredient in the product, and the marketer of the product. CRN strongly recommends that ODS include additional data fields in the DSLD for confidential information that is visible to FDA only. This information would not be accessible to the public, even if requested through a Freedom of Information Act (FOIA) request, because it would include commercial confidential information.

Specifically, CRN recommends that the DSLD be expanded to allow FDA to identify who manufactures and packages products in the DSLD. This information would be particularly useful for FDA when the manufacturer or packager of the product is different from the marketer and would allow FDA to directly contact the appropriate party if necessary to perform its regulatory functions. The recommended additional fields include: the company name and address of all facilities that manufacture the product; company name and address of all facilities that package the product if different from manufacturing facilities; name, address, phone number and email address of person submitting the label.

Additional Comments

CRN understands that the current administrator of the DSLD, who is contracted to manage the DSLD, also maintains a separate and distinct for-profit database. The current

database administrator also uses product data that are provided through its government contract with ODS to populate its for-profit product. CRN understands that all information in the DSLD is publicly available for download and, therefore, there are no limitations on how it may be used. However, we have serious concerns that the data entered by the administrator for the DSLD are directly and concurrently being utilized for a for-profit product. CRN recommends ODS provides assurances that information provided to the DSLD is not used to directly benefit any commercial for-profit companies, and that this issue is taken into consideration when the current contract expires and ODS reviews potential candidates for the DSLD administrator.

Thank you for considering our comments. Please do not hesitate to contact us should you have questions.

Sincerely,

Senior Vice President, Scientific & Regulatory Affairs

Enclosure (1)

Council for Responsible Nutrition
The Science Behind the Supplements

Voluntary Dietary Supplement Product Registry
Framework – Reviewed by CRN's Board of Directors 10/23/2015

I. Dietary Supplement Product Notification

A. Any firm that manufactures (including re-packers and re-labelers) or distributes under its own name a dietary supplement intended for sale in the U.S. should submit a product notification to the product notification database.
B. A product notification is required for each unique product formulation.
C. Each dietary supplement product notification includes a unique product identifier assigned to the unique product formulation that is the subject of the notification.
D. Product notification is done using an electronic format.
E. The database administrator automatically issues an electronic receipt confirmation once a product notification has been submitted.
F. Confirmation of the receipt of a dietary supplement notification does not convey FDA approval or endorsement of the product.

II. Party responsible for submitting dietary supplement production notifications

A. A firm may self-designate as the "Responsible Party" or assign a "Responsible Party" to submit the product notifications on their behalf.

III. Dietary supplement product notification database

A. Who administers the product notification database?
    i. Either FDA or a designated third-party serves as the database administrator depending on whether dietary supplement product notification is mandatory or voluntary.
A. The product notification database administrator has the responsibility to:
    i. Assign the Responsible Party identifier to a Responsible Party
    ii. Receive and confirm receipt of all electronic dietary supplement product notification submissions
    iii. Manage different levels of access to the information in dietary supplement product notifications for FDA and the public

IV. Unique product formulation

A. A unique product formulation comprises specific dietary ingredients, including their quantitative amounts, and ingredients that are sources of dietary ingredients, and is limited to a single product dosage form.

B. Product formulation changes that would require an update to the dietary supplement product notification include (a) change to the identity or quantitative amount of a dietary ingredient, (b) change to the identity of an ingredient that is a source of a dietary ingredient, and (c) change to the product dosage form.

V. Unique product identifier

A. The unique product identifier has two numeric parts set in a pre-determined configuration(s), preceded by a prefix to designate the product is a dietary supplement (see *Figure 1.*)

   i. The prefix is the same for all unique product identifiers.

   ii. First numeric part: Responsible Party identifier assigned by the product notification database administrator to the Responsible Party.

      1. The Responsible Party identifier should be different from NDC labeler codes which have either 4 or 5 digits.

   iii. Second numeric part: Product identifier self-assigned by the Responsible Party that is unique to the specific product formulation that is the subject of the product notification.

Figure 1. Possible configurations for the unique product identifier

Common Prefix ⇓	**Responsible Party Identifier** ⇓		**Product Identifier** ⇓	**Generic Example** ⇓
DS	N N N N N N	—	N N N	DS 123456 — 789
		OR		
DS	N N N N N N	—	N N N N	DS 009876 — 5432

N = any number from 0 – 9, inclusive

VI. Information required in the dietary supplement product notification

A. Information accessible to FDA and the public

- Unique product identifier

- Responsible Party name, address, phone number, and email address
- Brand name(s) under which the product is sold
- Product name(s) under which the product is sold
- Product dosage form
- A list of all dietary ingredients and their quantitative amounts as declared on the Supplement Facts Panel
- A list of all ingredients that are sources of dietary ingredients
- A copy of one representative product label

B. Information accessible to only FDA
   - Company name and address of all facilities that manufacture the product
   - Company name and address of all facilities that package the product if different from manufacturing facilities
   - Name, address, phone number and email address of person submitting the notification
   - Certification that the information submitted is true and accurate and that the person submitting the notification is authorized to do so

VII. Submission of a dietary supplement product notification, an update to an existing product notification, or notification of a product discontinuation

A. A dietary supplement product notification should be submitted within 30 days of initial marketing of the product.
B. Any change to the required information in an existing product notification should be submitted as an update within six months of initial marketing of the change.
C. Discontinuation of a dietary supplement product should be notified as an update to an existing product notification within six months of the last sale date.

VIII. Removal a dietary supplement product notification for a discontinued product from the database

A. There should be provisions for the removal of a dietary supplement product notification for a discontinued product from the database (to be discussed later).