CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

December 31, 2015

Mr. Richard Bailen, MBA, MHA
Office of Dietary Supplements
National Institutes of Health
6100 Executive Boulevard, Room 3B01
Bethesda, MD 20892-7517

sent electronically to: ODS@nih.gov

Re: Notice of Opportunity for Public Comment on the Dietary Supplement Label Database

Dear Mr. Bailen:

These comments are submitted on behalf of the Consumer Healthcare Products Association ("CHPA") in response to the October 29, 2015 Federal Register notice entitled "Notice of Opportunity for Public Comment on the Dietary Supplement Label Database". CHPA is a member-based association representing the leading manufacturers and distributors of non-prescription (or over-the-counter; OTC) medicines and dietary supplements. CHPA appreciates the opportunity to provide information on features to add and potential functionality improvements to make the Dietary Supplement Label Database (DSLD) a more useful tool for regulators, consumers and other users of the database.

Given the increasing number of dietary supplement products available on the US market since the passage of the Dietary Supplement Health and Education Act in 1994, it is useful to have a central repository of information on these products available to consumers and other potential users of the database. CHPA and their member companies marketing dietary supplements see a number of potential benefits of the DSLD including the following:

- Enhanced consumer understanding of legally-marketed dietary supplement products and their intended uses
- Increased industry transparency to regulators, policy makers and consumers
- Demonstration of a responsible industry dedicated to marketing quality products
- Enhanced ability of FDA to take enforcement action against those marketing illegal products

While we feel there are many potential benefits associated with the database we also respectfully request that the Office of Dietary Supplements (ODS) clearly identify what the benchmark for success will be as the database is modified. Awareness of the database and its potential uses amongst consumers and industry is currently limited, based on our members' experience. For any suggested improvemenets to be useful ODS needs to identify what added benefit they are expected to achieve.

CHPA member companies marketing dietary supplements ask that ODS ensure that a quality control process is in place to verify that any information added to the database is up to date and correct. In some cases, industry does not control the information contained in the DSLD; as such, it is critical that appropriate safeguards are maintained in order to ensure that consumers and other users of the database can retrieve accurate information. There are currently several examples of products contained within the DSLD that are not intended for oral ingestion and thus by definition are not dietary supplements.[1]

It may also be useful for ODS to create a process to catalogue historic labels. This would allow a record to be kept of the historic use of a dietary ingredient and create a convenient source for determining whether a dietary ingredient was marketed prior to October 15, 1994 (DSHEA). We also suggest that ODS add separate fields to indicate whether the dietary ingredient is a 'New Dietary Ingredient' or an 'Old Dietary Ingredient' as well as to indicate how each dietary ingredient is related to the DSHEA definition (vitamin, mineral, amino acid, herb or botanical, dietary substance or a concentrate or metabolite of the above).

To enhance the usefulness of the DSLD for consumers, ODS should create a field within the DSLD to allow for searches based on the primary health or nutritional benefit provided. Examples of such fields could include bone, energy, heart, immune, joint, memory, mood, multivitamin, performance, sleep, or vision.

[1] Efficient Laboratories Inc. Spot Out; truDERMA and uLEAN topical patches; BRONSON Laboratories, Omega-7 Wrinkle Defense lotion

One of the potential benefits of this improved database would be the ability of regulators to identify those who manufacture and market illegal products masquerading as dietary supplements. While this process would require appropriate testing to ensure accurate identification of violative products, FDA and the American Herbal Products Association currently maintain lists of products illegally marketed as dietary supplements (containing active pharmaceutical ingredients or other unallowed or undeclared ingredients).

ODS could also include confidential fields containing factual public information for use by the agency to track regulatory issues and resolutions. Example fields include the following:

- 30-day notification letter been submitted to FDA for product
- warning letters
- recalls
- 483s
- Presence of banned ingredients

In previous comments to ODS[2] we identified more frequent collaborative efforts with industry as a way to obtain more regular feedback and to be better positioned to take advantage of opportunities. Greater industry participation in the process may be beneficial, perhaps through regularly scheduled updates from ODS or via government/industry participation in a seminar series similar to the jointly-sponsored CHPA and Center for Drug Evaluation and Research series which has been ongoing for a number of years.

[2] CHPA comments on the ODS Strategic Plan 2010-2014 Progress Report; March 6, 2015

We continue to believe that through these types of efforts we could enhance the functionality of the database and provide enhanced information for consumers, regulators and other users of the DSLD. We look forward to working with ODS staff on these efforts to enhance the functionality of the DSLD and would be happy to have further discussions regarding these comments.

Sincerely,

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