ChromaDex Corp.
Form 10-K
March 29, 2013

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the fiscal year ended December 29, 2012

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

Commission file number 000-53290

CHROMADEX CORPORATION
(Exact name of Registrant as specified in its Charter)

Delaware (State or other jurisdiction of incorporation)	26-2940963 (I.R.S. Employer Identification No.)
10005 Muirlands Blvd. Suite G, Irvine, California (Address of Principal Executive Offices)	92618 (Zip Code)

Registrant's telephone number, including area code (949) 419-0288

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of Each Exchange on Which Registered
N/A	N/A

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [ ] No [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “accelerated filer,” “large accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer [ ] Accelerated Filer [ ] Non-accelerated filer [ ] (Do not check if smaller reporting company)
Smaller Reporting Company [X]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes [ ] No [X]

As of June 30, 2012, the aggregate market value of the common stock held by non-affiliates of the Registrant was approximately $37,933,178.
Number of shares of common stock of the registrant outstanding as of March 28, 2013 : 96,507,883

DOCUMENTS INCORPORATED BY REFERENCE None.

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PART I

CAUTIONARY NOTICE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Form 10-K") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements reflect the current view about future events. When used in this Form 10-K the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan" or the negative of these terms and similar expressions relate to us or our management identify forward looking statements. Such statements, include, but are not limited to, statements contained in this Form 10-K relating to our business, business strategy, products and services we may offer in the future, sales and marketing strategy and capital outlook. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statement of historical fact nor guarantees of assurance of future performance. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward looking statements include, but are not limited to, a continued decline in general economic conditions nationally and internationally; decreased demand for our products and services; market acceptance of our products; the ability to protect our intellectual property rights; impact of any litigation or infringement actions brought against us; competition from other providers and products; risks in product development; inability to raise capital to fund continuing operations; changes in government regulation; the ability to complete customer transactions and capital raising transactions, and other factors (including the risks contained in Item 1A of this Form 10-K under the heading "Risk Factors") relating to our industry, our operations and results of operations and any businesses that may be acquired by us. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we undertake no obligation to and do not intend to update any of the forward-looking statements to conform these statements to actual results.

Item 1. Business

Company Overview

The business of ChromaDex Corporation is conducted by our principal subsidiaries, ChromaDex, Inc., Chromadex Analytics, Inc. and Spherix Consulting, Inc. ("Spherix"). ChromaDex Corporation and its subsidiaries (collectively referred to herein as "ChromaDex" or the "Company" or, in the first person as "we" "us" and "our") supplies phytochemi reference standards, which are small quantities of plant-based compounds typically used to research an array of potential attributes, and reference materials, related contract services, technical consulting and proprietary ingredients. We perform chemistry-based analytical services at our laboratory in Boulder, Colorado, typically in support of quality control or quality assurance activities within the dietary supplement industry. We recently acquired Spherix Consulting, Inc., which provides scientific and regulatory consulting to the clients in the food, supplement and pharmaceutical industries to manage potential health and regulatory risks. In 2011, we launched the BluScience retail dietary supplement products containing one of the proprietary ingredients, pTeropure, which we also sell as an ingredient for incorporation into the products of other companies. However, on March 28, 2013, we entered into an asset purchase and sale agreement with NeutriSci International Inc. ("NeutriSci") and consummated the sale of BluScience consumer product line to NeutriSci. For the fiscal years ended December 29, 2012 and December 31,

2011, our revenues were $11,610,494 and $8,112,610, respectively.

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We are a leading provider of research and quality-control products and services to the natural products industry. Customers worldwide in the dietary supplement, food & beverage, cosmetic and pharmaceutical industries use our products, which are small quantities of highly-characterized, research-grade, plant-based materials, to ensure the quality of their raw materials and finished products. Customers also use our analytical chemistry services to support their quality assurance activities, primarily to ensure the identity, potency and safety of their consumer products. We have conducted this core business since 1999.

We believe there is a growing need at both the manufacturing and government regulatory levels for reference standards, analytical methods and other quality assurance methods to ensure that products that contain plants, plant extracts and naturally occurring compounds distributed to consumers are safe. We further believe that this need is driven by the perception at the consumer level of a lack of adequate quality controls related to certain functional food or dietary supplement based products, as well as increased effort on the part of the Food and Drug Administration ("FDA") to assure Good Manufacturing Practices ("GMP").

Our core standards and contract service businesses provide us with the opportunity to become aware of the results from research and screening activities performed on thousands of potential natural product candidates. By selecting the most promising ingredients from this market-based screening model, which is grounded in primary research performed by leading universities and institutions, followed by selective investments in further research and development, new natural products-related intellectual property can be identified and brought to various markets with a much lower investment cost and an increased chance of success. The first of these proprietary compounds, pTeroPure, is our brand name for the compound, pterostilbene. Pterostilbene is a polyphenol and a powerful antioxidant that shows promise in a range of health related issues. We have in-licensed patents pending related to the use of pterostilbene for a number of these benefits, and have filed additional patents related to additional benefits, such as a patent jointly filed with University of California at Irvine related to its effects on non-melanoma skin cancer. We have successfully conducted a clinical trial, together with the University of Mississippi, related to its blood pressure lowering effects. We expect to conduct additional clinical trials on this compound and we anticipate entering the dietary supplement, animal health and, if clinical results are favorable, the pharmaceutical market. We believe that we have opportunities in the skin care market and we will continue to investigate developing these opportunities internally or through third party partners. We anticipate conducting additional clinical trials on other compounds in our pipeline to provide differentiation as we market these ingredients and support various health-related claims or obtain additional regulatory clearances.

With an addition of Spherix Consulting Inc., we now provide our clients in the food, supplement and pharmaceutical industries with effective solutions to manage potential health and regulatory risks. Our science-based solutions are for both new and existing products that may be subject to product liability and/or exposed to changing scientific standards or public perceptions; literature evaluations; and design and assessment of pre-clinical and clinical safety testing. We specialize in regulatory submissions for food and dietary supplement ingredients. For our clients involved in drug development within the pharmaceutical industry, we provide similar services as well as risk-based strategies, including intellectual property data and compliance gap identification, due diligence assessments and investigational new drug writing. We believe that the addition of Spherix will complement and expand our leadership in reference standards and services business. By providing a more comprehensive suite of science-based and regulatory services, we will be able to more efficiently advance products in the dietary supplement, food and beverage, animal health, cosmetic and pharmaceutical markets.

Company Background

ChromaDex, Inc. was originally formed as a California corporation on February 19, 2000. On April 23, 2003, ChromaDex Inc. acquired the research and development group of a competing natural product company called Napro Biotherapeutics (now Tapestry Pharmaceuticals) located in Boulder, Colorado. The assets acquired in this transaction

were placed in a newly-formed, wholly-owned subsidiary of ChromaDex named Chromadex Analytics, Inc., a Nevada corporation. On December 3, 2012, ChromaDex Inc. acquired a scientific and regulatory consulting company called Spherix Consulting Inc. located in the greater Washington D.C. area and Spherix Consulting Inc. became a wholly-owned subsidiary of ChromaDex, Inc.

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Our Strategy

Our business strategy is to identify, acquire, reduce-to-practice, and commercialize innovative new natural products and technologies, with an initial industry focus on the dietary supplement, nutraceutical, food and beverage, functional food, animal health, pharmaceutical and skin care markets. We plan to utilize our experienced management team to commercialize these natural product technologies by advancing them through any required regulatory approval processes, selectively conducting clinical trials, arranging for reliable and cost-effective manufacturing, and ultimately either directly selling the products or licensing the intellectual property to third parties. We plan to conduct clinical trials to (a) reinforce the health benefits that may be associated with our ingredients in support of sales made into the dietary supplement and food and beverage markets, (b) potentially improve the quality or specificity of FDA approved claim we can make with respect to these health benefits, and (c) potentially lead us toward pharmaceutical applications for our ingredients.

Commercialization of intellectual property: We believe that many of our products currently in development have the potential to spin off technologies that may themselves be independently capable of commercialization and becoming significant new revenue sources. We believe that new intellectual property can also be developed from our expansion into new markets.

Expansion and growth of the core business: We intend to continue to expand our phytochemical standards offerings, which is the core of our business. Currently, we have approximately 4,500 defined standards. We expect to add 500 to 1,000 new standards each year for the foreseeable future.

Expansion into new markets: We are developing business in new domestic and international markets. These markets include both the domestic and international botanical drug market and the market for novel therapeutic botanicals from Asia, South America and Africa. We have also added what we believe to be new and innovative product offerings, including the screening of compound libraries and the offering of value-added raw materials.

Expansion through acquisitions: We are a leader in the phytochemical standards market. We believe other smaller competitors are having difficulty expanding their revenue base and are prime candidates for acquisition by us. We believe that a long-term roll-up strategy could eventually lead to ChromaDex positioning itself as a provider of choice for phytochemical standards and libraries.

Overview of our Products and Services

We are headquartered in Irvine, California, and our analytical and research laboratory facility, Chromadex Analytics, is located in Boulder, Colorado. Chromadex Analytics operates a facility with 13,000 square feet of laboratory and office space. While we perform many of the contract services and research for our clients, Chromadex Analytics manufactures certain phytochemical reference standards, provides research and development, all analytical services and laboratory support for ChromaDex. Since 2003, we have invested in excess of $2 million in laboratory equipment, and we currently have personnel possessing over 150 years of combined pharmaceutical and natural products chemistry experience.

We have recently acquired Spherix, located in the greater Washington D.C. area. Spherix provides its clients in the food, supplement and pharmaceutical industries with effective solutions to manage potential health and regulatory risks.

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Current products and services provided are:

Dietary supplement and food ingredients. We offer bulk raw materials for inclusion in dietary supplements, food, beverage and cosmetic products. This is an area where we are increasing our focus, as we believe we can secure and defend our market positions through patents and long-term manufacturing agreements with our customers and vendors.

Supply of reference standards, materials & kits. Through our catalog, we supply a wide range of products necessary to conduct quality control of raw materials and consumer products. Reference standards and materials and the kits created from them are used for research and quality control in the dietary supplements, cosmetics, food and beverages, and pharmaceutical industries.

Supply of fine chemicals and phytochemicals. As demand for new natural products and phytochemicals increases, we can scale up and supply our core products in the gram to kilogram scale for companies that require these products for research and new product development.

Contract services. ChromaDex, through Chromadex Analytics, provides a wide range of contract services ranging from routine contract analysis for the production of dietary supplements, cosmetics, foods and other natural products to elaborate contract research for clients in these industries.

Consulting services. We provide a comprehensive range of consulting services in the areas of regulatory support, new ingredient or product development, risk management and litigation support. With an addition of Spherix, we now can provide and are now offering product regulatory approval and scientific advisory services.

Process development. Developing cost effective and efficient processes for manufacturing natural products can be very difficult and time consuming. We can assist customers in creating processes for cost-effective manufacturing of natural products, using “green chemistry.”

Products and services in development:

Anthocyanin. We are working to establish cost-effective methodologies for the efficient production of anthocyanins from genetically engineered bacteria. Anthocyanins are secondary plant metabolites that are mainly responsible for the colors in plant tissues, primarily reds, purples and blues. They are non-toxic and have been observed to possess antioxidant, anticancer and anti-inflammatory activities, making them attractive candidates in the pharmaceutical, dietary supplement and food colorants industries.

Nicotinamide riboside. We are working to establish cost-effective methodologies for the efficient production of nicotinamide riboside. Nicotinamide riboside, a recently discovered vitamin found naturally in milk, is a more potent version of the more commonly known niacin (vitamin B3). Nicotinamide riboside has shown promise for improving cardiovascular health, glucose levels and cognitive function and has demonstrated evidence of anti-aging effects.

Process scale manufacturing. We intend to invest in a pilot plant facility that has the capability of manufacturing at a process scale for products that have gone to market.

Phytochemical libraries. We intend to continue investing in the development of natural product based libraries by continuing to create these libraries internally as well as through product licensing.

Plant extracts libraries. We intend to continue our efforts to create an extensive library of plant extracts using our already extensive list of botanical reference materials.

Databases for cross-referencing phytochemicals. We are working on building a database for cross referencing phytochemicals against an extensive list of plants, including links to references to ethnopharmacological, ethnobotanical, and biological activity, as well as clinical evidence.

Intellectual property. We plan to utilize our expertise in natural products to license and develop new intellectual property that can be licensed to clients in our target industries.

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Sales and Marketing Strategy

Our sales platform for the chemical and analytical service business is based on direct, inside technical sales model. We hire technical sales staff with appropriate scientific background in chemistry, biology, biochemistry or other related scientific fields. Our sales staff currently operates out of our Irvine, California office and performs sales duties by using combinations of telemarketing, e-mail, tradeshows and customer visits. It also has customer service responsibilities. We plan to add outside field sales representatives in the future as needed. All sales staff are compensated based on a uniform basic pay model based on salary and performance-based bonus.

Spherix generates scientific and regulatory consulting revenue from an existing well-established list of Fortune 1000 customers and referrals. Our existing sales staff for the chemical and analytical service business will also generate leads for Spherix.

USA and Canada:

For our ingredients, core reference standards and analytical service business, we employ the use of a direct mail marketing strategy (catalogs, brochures and flyers) in combination with a range of the following marketing activities to promote and sell our products and services:

Tradeshows and conferences

Monthly newsletters (via e-mail)

Internet

Website

Advertising in trade publications

Press releases

We intend to continue to use a direct marketing approach to promote our products and services to all markets that we target for direct sales.

International:

For our core reference standards business, we use international distributors to market and sell to several foreign countries or markets. The use of distributors in some international markets has proven to be more effective than direct sales. Currently, we have exclusive distribution agreements in place with the following distributors for the following countries or regions:

Europe (LGC Limited)

South America (JMC, Inc.)

Korea (Dong Myung Scientific Co.)

India (LGC Promochem India Pvt. Ltd.)

We also use non-exclusive distributors for each of the following countries or groups of countries:

Japan

Australia and New Zealand

China

Indonesia, Malaysia, Singapore and Thailand

Mexico

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We may decide in the future to make non-exclusive distributors who show significant productivity in their designated market exclusive distributors in such markets.

Business Market

According to the Natural Marketing Institute, the Dietary Supplement, Functional Food and Beverage, and Natural Personal Care markets represent more than $250 billion in annual worldwide sales. The quality control and assurance of some of the products in these markets are, as previously noted, largely "under regulated." This scenario leads to the establishment of the basis of one of our business strategies: concentration on the overall content of products, as well as active/marker components, uniformity of production, and toxicology of products in these markets in ways similar to analysis by other companies focused in the pharmaceutical industry. There is an increasing demand for new products, ingredients and ideas for natural products. The pressure for new, innovative products, which are "natural" or "green" based, cuts across all markets including food, beverage, cosmetic and pharmaceutical.

While we believe that doctors and patients have become more receptive to the use of botanical and herbal-based and natural and dietary ingredients to prevent or treat illness and improve quality of life, the medical establishment has conditioned its acceptance on significantly improved demonstration of efficacy, safety and quality control comparable to that imposed on pharmaceuticals. Nevertheless, little is currently known about the constituents, active compounds and safety of many botanical and herbal natural ingredients and few qualified chemists and technology based companies exist to supply the information and products necessary to meet this burgeoning market need. Natural products are complex mixtures of many compounds, with significant variability arising from growing and extraction conditions. The following developments are some that highlight the need for standards control and quality assurance:

The FDA published its draft guidance for GMPs for dietary supplements on March 13, 2003. The final rule from this guidance was made effective in June 2007, and full compliance was required by June 2010;

Regulatory agencies around the world have started to review the need for the regulation of herbal and natural supplements and are considering regulations that will include testing for the presence of toxic or adulterating compounds, drug/compound interactions and evidence that the products are biologically active for their intended use.

Business Model

We have taken advantage of both supply chain needs and regulatory requirements such as the GMPs for dietary supplements to build our core standards and analytical services businesses. We believe that we create value throughout the supply chain of the pharmaceutical, dietary supplements, functional foods and personal care markets. We do this by:

Combining the analytical methodology and characterization of materials with the technical support for the sale of reference materials by our clients;

Helping companies to comply with new government regulations; and

Providing value-added solutions to every layer of the supply chain in order to increase the overall quality of products being produced.

In addition, the recent acquisition of Spherix has enabled us to be a premier provider of product regulatory approval and scientific advisory services. We can now provide our clients in the food, supplement and pharmaceutical industries with effective solutions to manage potential health and regulatory risks. Our science-based solutions are for both new and existing products that may be subject to product liability and/or exposed to changing scientific standards

or public perceptions; literature evaluations; and design and assessment of pre-clinical and clinical safety testing. We specialize in regulatory submissions for food and dietary supplement ingredients. For our clients involved in drug development within the pharmaceutical industry, we provide similar services as well as risk-based strategies, including intellectual property data and compliance gap identification, due diligence assessments and investigational new drug writing. By providing a more comprehensive suite of science-based and regulatory services, we will be able to more efficiently advance products in the dietary supplement, food and beverage, animal health, cosmetic and pharmaceutical markets.

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We believe we are now in a position to expand this aspect of our business and, more importantly, capitalize on additional opportunities in product development and commercialization of various kinds of intellectual property that we have largely discovered and acquired through the sales process associated with our standards and services, businesses.

Our core standards and contract service businesses provide us with the opportunity to become aware of the results from research and screening activities performed on thousands of potential natural product candidates. By selecting the most promising ingredients from this market-based screening model, which is grounded in primary research performed by leading universities and institutions, followed by selective investments in further research and development, new natural products-related intellectual property can be identified and brought to various markets with a much lower investment cost and an increased chance of success. The first of these proprietary compounds, pTeroPure, is our brand name for the compound, pterostilbene. Pterostilbene is a polyphenol and a powerful antioxidant that shows promise in a range of health related issues. We have in-licensed patents pending related to the use of pterostilbene for a number of these benefits, and have filed additional patents related to additional benefits, such as a patent jointly filed with University of California at Irvine related to its effects on non-melanoma skin cancer. We have successfully conducted a clinical trial, together with the University of Mississippi, related to its blood pressure lowering effects. We expect to conduct additional clinical trials on this compound and we anticipate entering the dietary supplement, animal health and, if clinical results are favorable, possibly the pharmaceutical markets with it. We believe that we have opportunities in the skin care market and we will continue to investigate developing these opportunities internally or through third party partners. We anticipate conducting additional clinical trials on other compounds in our pipeline to provide differentiation as we market these ingredients and support various health-related claims or obtain additional regulatory clearances.

We continue to identify and in-license novel, proprietary compounds with significant potential health benefits. Among these next generation compounds are anthocyanins, which are compounds responsible for the dark pigment found in certain berries and flowers, and nicotinamide riboside, a compound similar to the B-vitamin, niacin. Like pTeroPure®, these compounds also have potential in multiple markets.

Government Regulation

Some of our operations are subject to regulation by various United States federal agencies and similar state and international agencies, including the FDA, the Federal Trade Commission (“FTC”), the Department of Commerce, the Department of Transportation, the Department of Agriculture and other state and international agencies. These regulators govern a wide variety of production activities, from design and development to labeling, manufacturing, handling, selling and distributing of products. From time to time, federal, state and international legislation is enacted that may have the effect of materially increasing the cost of doing business or limiting or expanding our permissible activities. We cannot predict whether or when potential legislation or regulations will be enacted, and, if enacted, the effect of such legislation, regulation, implementation, or any implemented regulations or supervisory policies would have on our financial condition or results of operations. In addition, the outcome of any litigation, investigations or enforcement actions initiated by state or federal authorities could result in changes to our operations being necessary and in increased compliance costs.

FDA Regulation

Dietary supplements are subject to FDA regulations. For example, the FDA’s final rule on GMPs for dietary supplements published in June 2007 requires companies to evaluate products for identity, strength, purity and composition. These regulations in some cases, particular for new ingredients, require a notification that must be submitted to the FDA along with evidence of safety. In addition, depending on the type of product, whether a dietary supplement, cosmetic, food, or pharmaceutical, the FDA, under the Food, Drug and Cosmetic Act, or FDCA, can

regulate:

- product testing;
- product labeling;
- product manufacturing and storage;
- premarket clearance or approval;
- advertising and promotion; and
- product sales and distribution.

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The FDCA has been amended several times with respect to dietary supplements, most notably by the Dietary Supplement Health and Education Act of 1994, known as "DSHEA." DSHEA established a new framework for governing the composition and labeling of dietary supplements. Generally, under DSHEA, dietary ingredients that were marketed in the United States before October 15, 1994 may be used in dietary supplements without notifying the FDA. However, a "new" dietary ingredient (a dietary ingredient that was not marketed in the United States before October 15, 1994) is subject to a new dietary ingredient, or NDI, notification that must be submitted to the FDA unless the ingredient has previously been "present in the food supply as an article used for food" without being "chemically altered." An NDI notification must provide the FDA with evidence of a "history of use or other evidence of safety" establishing that the use of the dietary ingredient "will reasonably be expected to be safe." An NDI notification must be submitted to the FDA at least 75 days before the initial marketing of the NDI. There can be no assurance that the FDA will accept the evidence of safety for any NDIs that we may want to commercialize, and the FDA's refusal to accept such evidence could prevent the marketing of such dietary ingredients. The FDA is in the process of developing guidance for the industry that will aim to clarify the FDA's interpretation of the NDI notification requirements, and this guidance may raise new and significant regulatory barriers for NDIs.

In order for any new ingredient developed by us to be used in conventional food or beverage products in the United States, the product would either have to be approved by the FDA as a food additive pursuant to a food additive petition, or FAP, or be generally recognized as safe, or GRAS. The FDA does not have to approve a company's determination that an ingredient is GRAS. However, a company can notify the FDA of its determination. There can be no assurance that the FDA will approve any FAP for any ingredient that we may want to commercialize, or agree with our determination that an ingredient is GRAS, either of which could prevent the marketing of such ingredient.

Advertising Regulation

In addition to FDA regulations, the FTC regulates the advertising of dietary supplements, foods, cosmetics, and over-the-counter, or OTC, drugs. In recent years, the FTC has instituted numerous enforcement actions against dietary supplement companies for failure to adequately substantiate claims made in advertising or for the use of false or misleading advertising claims. These enforcement actions have often resulted in consent decrees and the payment of civil penalties, restitution, or both, by the companies involved. We may be subject to regulation under various state and local laws that include provisions governing, among other things, the formulation, manufacturing, packaging, labeling, advertising and distribution of dietary supplements, foods, cosmetics and OTC drugs.

In addition, The National Advertising Division of the Council of Better Business Bureaus ("CBBB") reviews national advertising for truthfulness and accuracy. The NAD uses a form of alternative dispute resolution, working closely with in-house counsel, marketing executives, research and development departments and outside consultants to decide whether claims have been substantiated.

International

Our international sales of dietary ingredients are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. In addition, the export by us of certain of our products that have not yet been cleared or approved for domestic distribution may be subject to FDA export restrictions. We may be unable to obtain on a timely basis, if at all, any foreign government or United States export approvals necessary for the marketing of our products abroad.

Regulation in Europe is exercised primarily through the European Union, which regulates the combined market of each of its member states. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to dietary ingredients.

Competitive Business Conditions

For reference standards and analytical testing services, we face competition within the standardization and quality testing niche of the natural products market, though we know of no other companies that offer both reference standards and testing to their customers. Below is a current list of certain competitors. These competitors have already developed reference standards or contract services or are currently taking steps to develop botanical standards or contract services. Of the competitors listed, some currently sell fine chemicals, which, by default, are sometimes used as reference standards, and others are closely aligned with our market niche so as to reduce any barriers to entry if these companies wish to compete. Some of these competitors currently offer similar services and have the scale and resources to compete with us for larger customer accounts. Because some of our competitors are larger in total size and capitalization, they likely have greater access to capital markets, and are in a better position than we are to compete nationally and internationally.