

The Solid Dose

July 2010

Nutritional and Food Supplements Edition



In This Issue:

- Dietary & Nutritional Supplements – A Changing Landscape
- Conversation with... Carl Mroz, Director - Regulatory Affairs
- Evaluation of Two Redesigned Continuous Coating Machines
- Managing Costs to Maintain a Competitive Edge
- Case Study – Design & Qualification of a New Film Coating Operation
- Product Spotlight
- Colorcon Tools
- Colorcon News

Dietary & Nutritional Supplements – A Changing Landscape

*Author: Jim Coward
Vice President – Corporate Development*

In this edition of *The Solid Dose*, we focus on the dietary and nutritional supplement market, which generated about \$81.2 billion in sales worldwide in 2009. The market is expected to reach \$83.6 billion in 2010.¹ Multivitamins make up a major portion of this market and are expected to grow 7.5% through this year.² The growth of this market is being influenced by several factors including an aging population and an increase in chronic health conditions such as diabetes and heart disease resulting from poor nutritional habits. Specific supplements to support eye, joint and heart health, and other conditions of aging are expected to see double digit growth.²

Per capita spending is expected to increase along with a growing global middle class that has more income to spend on health care (Espicom Business Intelligence). Consumers are becoming more proactive in self care and using supplements to prevent illness. Currently the United States generates the majority of global sales, Western Europe is second, and Japan third. However, China is expected to out pace Japan due to the growing interest of its large middle class in nutrition and supplements. Other growing markets include Brazil, India, and Eastern Europe.²

As our customers involved in this market know, there are many challenges projected for the future. In particular, the regulatory landscape is becoming harder to navigate. New legislation is being developed around the world leaving manufacturers dealing with new regulations or potential changes. These changes

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Conversation with...

Carl Mroz, Director - Regulatory Affairs



Are you faced with trying to keep up with changing regulations and different legislation around the globe? That is why Colorcon® – Your Formulation

Partner™ has resources like Carl Mroz. As the Director of Regulatory Affairs, Mroz is closely involved with international regulatory activities that take place in the pharmaceutical and nutritional industries. For Colorcon, that means we are always current on changing regulations and legislative differences from a worldwide perspective. For our customers, that knowledge opens doors to opportunities for formulating with an understanding of what is acceptable around the world.

During our conversation with Mroz, we delve into those legislative differences and see how Colorcon's involvement continues to make an impact on the industry - all to benefit our customers.

Q: How are coating materials and colors regulated under food and dietary supplements (nutritionals) in Europe?

A: In the European Union (EU), coating materials that form part of a food supplement product need to be either approved food additives or food ingredients.

Food additives are substances added to food intentionally for a technological purpose. The EU has a list of food additives formally approved in terms

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► Dietary & Nutritional Supplements – A Changing Landscape

are affecting everything from what non-dietary ingredients can be used to what health claims can be made.² Furthermore, the differences in these regional regulations, from country to country, make it difficult for manufacturers to know if their product complies with the requirements of their target market. Good Manufacturing Practices (GMPs) are at the center of these regulatory changes. GMPs are fundamental to ensure consumer safety and trust in products and are driving an increased need for supply chain controls and traceability. As a result, there is much more focus on assuring that each component used in these products meets the appropriate regional requirements.

The nutritional segment has been a focal point for Colorcon for many years and we invested in both the expertise and products to meet the challenges. Colorcon has multiple technical and regulatory approved options to assist in development of nutritional and dietary supplements, including core excipients and immediate and delayed release film coatings, which can be custom formulated. Our Global Regulatory Affairs group can guide the custom formulation in terms of polymer, plasticizer, and colorant options to meet key regional regulatory requirements. Colorant options that are derived from natural sources are also available to ensure your product is label friendly when required. All of our products are manufactured from materials carefully selected to meet approved regulations for food or color additives and our suppliers are all fully qualified.

It is evident that this market will remain very competitive. Colorcon products and services offer advantages to help you successfully position your products, remain competitive, and accelerate your product to market. Our high performance film coatings may be used at higher solids concentration and faster spray rates with less water evaporation, leading to less energy consumption and increased efficiency. Custom color matching and rapid turnaround for sampling helps move your product to the consumer quicker.

Consumer appeal is an important qualifier for consumer purchase. Colorcon products can help your products be more appealing by masking objectionable taste and odor. Our Nutrateric[®], nutritional enteric coating system, is an excellent option for both tablets and soft gelatin capsules. Film coating also eases the ability to swallow dietary and nutritional products, which often tend to be somewhat larger in size. Additionally, to help your products stand out in the marketplace, Colorcon offers branding opportunities through high gloss and special effects coatings.

For more information on our products and services specially designed for the dietary and nutritional industry click [here](#).

1. *Nutritional Business Journal Global Supplement & Nutrition Industry Report 2010*

2. *International Alliance of Dietary/Food Supplement Associations – DCAT 2010*

► Conversation with... Carl Mroz

of safety. Some are restricted to the category of food that may be used and some have quantitative restrictions. For each approved food additive, the EU also has purity requirements in the form of a specification. Only substances that are approved and meet the relevant criteria of purity can be given an “E” number designation. For example, E 464 denotes hydroxypropyl methyl cellulose, which meets the purity requirements. Colors are considered to be one category of food additive. Some colors that may be added to food products, including food supplements, may be used without restriction and others have a maximum quantitative limit.

On the other hand, food ingredients are substances such as sugars and starches, which are consumed as part of the normal diet. Food ingredients used in this application must be safe for human consumption and meet the general requirements of Regulation (EC) 178/2002.

Q. What is the impact of regulation changes on the use of colorants in Europe?

A. Currently, the EU is in the middle of an overhaul of its legislation regarding food additives and flavors. This exercise is commonly known as the Food Improvement Agents Package (FIAP). Although this overhaul is intended to reformat existing legislation, without making substantial change, the opportunity is also being used to 'tweak' some specific areas. It is the FIAP process that introduced into European legislation the need for food products containing some specific colors to be labeled with a warning with respect to potential activity or attention issues in children.

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Evaluation of Two Redesigned Continuous Coating Machines

Author: Laura Scattergood
Manager, Film Coating

Continuous film coating processes have been utilized for many years on high-volume nutritional products due to their high production rates. The elongated spray zone and shallow bed depth of continuous coating units ensure that the tablets are presented with high frequency to the spray zone. This promotes coating uniformity in a relatively short period of time. The recent improvements and redesign of continuous coating units have enhanced coating uniformity and reduced product losses, making this process more interesting to companies using functional and non-functional film coatings. Trials conducted by Colorcon examined two redesigned continuous coating pans in order to evaluate the effectiveness of the improvements made to the pan designs.

In one study, multivitamin tablets were coated with Opadry® II, high performance film coating system, in both batch and continuous modes in the O'Hara Technologies HVCC-3015 continuous coating machine. By running the

continuous coating machine in a batch-to-continuous-batch mode, there was no loss of product during start-up and shutdown of the pan. The design changes to the continuous coating machine produced very good color development and uniformity in both a batch mode, as well as in the continuous mode.

An additional set of trials was run on the redesigned Thomas

Engineering continuous coating system. In these trials, soft gelatin capsules were coated with Nutrateric®, nutritional enteric coating system. Nutrateric is an aqueous, delayed release coating system designed specifically to meet the regulatory requirements for dietary supplement, nutritional, and herbal products in North America and Europe. The redesign of the Thomas Engineering continuous coating machine allowed for the application of recommended weight gains (3% - 4%) of Nutrateric in only one pass through the unit. Samples of the soft gelatin capsules were taken throughout the process and tested for resistance to simulated gastric fluid as a measure of coating uniformity and delayed release functionality. All of the samples of Nutrateric coated soft gelatin capsules exhibited good enteric protection.



► Conversation with... Carl Mroz

Q: What are the main differences between the US vs. EU regulations?

A: One main difference in legislation relates to the list of substances that may be legally used in a dietary supplement in the US and the list of substances that may be used in food supplements in Europe. Although there is much overlap between the two lists, there are many substances that are allowed in the US, but not allowed in Europe and vice versa. One example of this is the respective lists of permitted colorants. Iron oxide is a widely used color for food supplements in Europe, but its use is not allowed currently in the US. In the US, it is possible to use materials in dietary supplements that fall into the classification of Generally Recognized As Safe (GRAS). However, such a classification scheme does not exist outside the US.

Q: Do other major geographies of the world have different regulations?

A: In some parts of the world, for example India and China, food supplement products are not legislated as foods, but as medicinal products. In these cases, the products must be licensed in the same way as drug products and their components selected according to pharmaceutical precedence of use.

Q. How has the Colorcon Regulatory Department helped the industry by introducing new materials for use in Europe and other jurisdictions?

A. Colorcon has always been very active in initiating change to national legislation, especially if there is a barrier to the use of best technologies. An excellent example of this is with polyvinyl alcohol (PVA) coatings of food supplement products. The use of PVA has great technological advantages

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► Evaluation of Two Redesigned Continuous Coating Machines



The results of both trials support the assertion that these redesigned continuous coating units show significant improvements in coating uniformity and reduction in product loss.

For further details on this work, please reference the attached data sheets:

[Opadry II - Study Link \(PDF 210.62 KB\)>>](#)

[Nutrateric - Study Link \(PDF 78.51 KB\)>>](#)

Managing Costs to Maintain a Competitive Edge

*Author: Charlie Cunningham
Sr. Manager, Product Development*

With price competition on the rise, dietary/food supplement manufacturers are looking for ways to lower operating costs while increasing the quality of their finished product – a tough challenge to meet.

Applying a film coating to tablets provides numerous product quality improvements, yet the process is sometimes perceived as unnecessary. Conversely, manufacturers who readily acknowledge the quality benefits of film coatings struggle to find process improvements to lower their production costs. In both cases, Colorcon is able to help.

We conducted a study comparing the effect of film coating formulations in reducing or preventing coating defects on soft and friable multivitamin tablets. In the study, use of a PVA-based film coating reduced the amount of coating material required by 35% and lowered the coating processing time by 50%.

[Study Link \(PDF 345.017 KB\)>>](#)

► Conversation with... Carl Mroz

in terms of moisture protection of coated tablets and reduces the need for expensive packaging. It also offers efficiency improvements in the actual coating process. Colorcon has petitioned internationally to add PVA to the list of permitted food additives, so it can be used in conjunction with food supplements. In the US, Colorcon coordinated various safety studies that concluded with PVA becoming GRAS for this application in 2004. In the EU, this project has now also been fruitful in that PVA will be allowed for this application by mid 2011.

Q. How does Colorcon help in formulating coatings that would be acceptable in the EU and the US?

A. With years of experience in the area of formulating premixed products for coating solid oral dosage forms, Colorcon is ideally situated to match our product with both the substrate to be coated and the equipment that will be used. Having global interest, Colorcon participates actively in various trade organizations around the world so we are aware of upcoming changes. Our participation gives us the opportunity to comment on modifications and to ensure good science is being used to execute changes to legislation. In addition, Colorcon has developed internal databases to maintain the knowledge to work within any regulatory restrictions applied to specific components. For example, we continuously monitor regulations regarding acceptable colorants to ensure information is always current. The sum of all these factors place Colorcon in a perfect position to provide a customized solution to enable our customers to achieve their goals.

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► Case Study – Design & Qualification a New Film Coating Operation

Author: Peter Scanlon
Business Development Manager

The dietary supplements industry in Western Europe represents about 20% of the global market. In Eastern Europe, the market continues to grow at a double-digit rate driven by individual markets of food supplements, vitamins, herbal products and others.

In this price-sensitive market, competition among contract manufacturers is high. As a result, the goal of offering their clients shorter lead times, improved quality products, low-cost services and regulatory support is a competitive advantage.

Colorcon can leverage its knowledge and position within the pharmaceutical marketplace to help contract manufacturers achieve these goals. In the attached case study, Colorcon Limited supported Bioshell Teoranta, a contract manufacturer, to revise a key part of their manufacturing process, helping them meet and exceed expectations of their clients. This example demonstrates a win-win opportunity for the contractor and their end customer.

[Study Link \(PDF 39.96 KB\)>>](#)

Colorcon Tools

Colorcon Color Guide™

Permitted colorants for use in pharmaceutical or nutritional supplements are different around the world, making color selection a complex and sometimes time-consuming activity.



The Colorcon Color Guide™ is an easy-to-use reference tool designed to help. The guide shows color groups and helps pinpoint choices based on acceptable pigments for the major regulatory regions of the world.

To request a copy, click [here](#).

► Conversation with... Carl Mroz

Carl Mroz and Colorcon's entire global regulatory network are tightly integrated into all functions including, New Product Development, Technical Service, Production, Sales, and Marketing to ensure all Colorcon products meet the regional legislative standards for the markets where they are used.

For more information on US & Europe regulatory legislation, please view our on-demand nutritional webinars:

Carl Mroz, [New Solutions for Coating Food Supplement Solid Dose Products - Meeting Changing European Regulations](#)

Dave Schoneker, [Navigating the Changing Regulatory and GMP Environment in the United States for Non-Dietary Ingredients](#)

Product Spotlight...

Nutrateric® Nutritional Enteric Coating System



The use of delayed release coatings is a convenient and

effective way to improve consumer appeal to dietary supplement products by reducing unpleasant flavors and odors (eg, fish oil softgels and garlic tablets), enhancing the stability of natural ingredients and by improving overall product performance.

Nutrateric is an aqueous enteric coating system designed specifically to meet the regulatory requirements for dietary supplement, nutritional and herbal products in Europe, the United States and other North American regions. Self-affirmed GRAS status and adoption of Council Directive 2006/52/EC allows Nutrateric to be

Colorcon News

Colorcon Receives Award for Quality

Colorcon do Brasil Ltda is the proud winner of the Sindusfarma (Syndicate of Pharmaceutical Industry in the State of São Paulo) 2010 Quality Award for Suppliers of Raw Materials (Pharmaceuticals and Excipients). The award was presented Monday evening, May 24th, during the HSBC Brasil Ceremony



with approximately two thousand people in attendance. This year marked Colorcon's sixth time being recognized in this category, an achievement we hold in highest regard.

The Sindusfarma quality awards were created to recognize companies that help raise quality standards, ensure

that drugs meet sanitary specifications and provide products that have the quality the public demands. Sindusfarma brings together 120 national and international pharmaceutical companies, which account for more than 80% of sales of the pharmaceutical market in Brasil.

Press Release - Colorcon Upgrades Brasil Laboratory to Include Organic Solvent Processing Suites!

For complete Press Release – click [here](#)

Product Spotlight...

used on dietary supplements across the United States and Europe. It also features a unique patent pending technology specifically developed for nutritional applications.

Nutrateric offers reliable and reproducible performance as it is optimized for use on tablets and soft gelatin capsules using a fully aqueous coating system, which is simple to prepare and apply, and meets dietary supplement enteric disintegration requirements. Nutrateric is also more cost effective than other available technology, because enteric can be achieved at low levels of coating and features rapid application using standard processing equipment. Nutrateric is not only cost effective, but adds value back to your product as well. Being delayed release differentiates your product from others and appeals to consumers through enhanced product presentation and performance.

Nutrateric and Colorcon offer all the advantages necessary to surpass other systems offered in the highly cost-competitive dietary and nutritional supplement marketplace.

For more information, click [here](#).

For more information on any products or services mentioned in this newsletter, please [Contact Us!](#)

To access previous versions of The Solid Dose, please click [here](#).



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