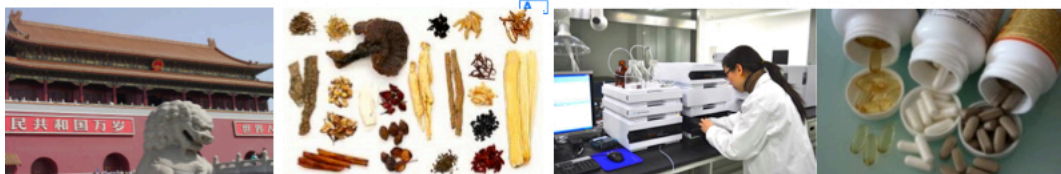


CHINA UPDATES

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China Considers Positive Changes for Dietary Supplement Industry

The regulatory management of China's dietary supplement industry has always been a controversial issue especially over the last 6 years. The current regulations require companies to apply for a registration with China's Food and Drug Administration. The registration itself is referred to as a "blue hat" registration because the logo resembles a blue hat. This process requires two to three years of administration procedures, rigorous testing and clinical trials. Furthermore, this is not an inexpensive endeavor. Once finalized, most registrations can cost upwards of \$100,000 or more per product depending on what claim is being made and what the ingredients are.

As the process is not at all transparent, registration agents are typically hired to assist in navigating the process and keeping the procedure moving forward. Of course this service is not free and adds to the overall investment in the blue hat.

The above system has allowed a select group of companies to monopolize the industry as they have invested heavily to obtain blue hat registrations in the 1990s. If we take a look at the numbers of registrations handed out only between 2010 -2103, we can see the great majority of these have been given to domestic companies. Here are the numbers: Domestic – 3,154 Foreign – 56.

It is a well known industry rumor that many of these domestic registrations are in fact being held by companies that look to sell them and make profits because transferring a registration from one company to another is faster than going through the entire process. Because the registration process is so costly in both time and capital, there are companies willing to pay for these "pre-registered" products in order to expedite their entry to market.

Now this is not to say the government is refusing to give registrations to foreign companies. It is a reflection of most foreign companies refusing to invest in such an unreasonable

regulatory system. The U.S. – China Health Products Association is regularly queried by global players with a flurry of “whys” such as: “Why does China treat dietary supplements as though they are drugs when they are regulated as food or nutritional products in the rest of the world; Why does China force companies to go through clinical trials and testing when these ingredients have decades of safety data and why must companies go through the process when similar or identical products have already received registrations, what’s with all the redundancies; why are some dietary supplements registration as OTC drugs, others as blue hat health foods, yet others as Traditional Chinese Medicine and others as food?” It makes for a very confusing landscape for consumers and is hurting the industry development.

The current regulations are seen not only as prohibiting the healthy development of the industry, but also as a barrier to trade. The U.S. – China Health Products Association recently released an export potential report, which showed that the U.S. dietary supplement industry is losing in excess of \$8 billion in exports to China as well as over 2,700 jobs that would be created as a result of said exports. Although this report focused on the U.S. industry, other global players as well as domestic players are all losing out. However, the association feels the biggest losers in this situation are the consumers as they are denied cutting edge dietary supplements that could help them live longer healthier lives and with China’s enormous elderly population looming this is a very important point...“healthier lives”.

Well the great news is there might be light at the end of the tunnel. This year China’s FDA has publicly stated that the dietary supplement (health food) industry will be revised and include a notification type system. As these proposals are still being debated, it is hard to say how much of that “light” gets through.

This Spring China’s National People’s Congress put forth legislation that would put an end to the blue hat system and allow dietary supplements to be handled with a notification type system. China’s Premier Li Keqiang has been stressing the decentralization of the government’s power over the market and wants to begin to open China to market forces. However, the above-mentioned reforms are being challenged.

There are two opposing sides to this ongoing struggle to develop China’s dietary supplement industry.

One idea as mentioned above is to do away with the “blue hat” regulatory system and place it under the overall “food safety law” regulation. Meaning dietary supplements or nutritional supplements would be handled more as a type of food, which would require companies to submit products on a notification basis to the government. This of course would streamline the “to market” process and solve almost all of the issues mentioned earlier.

Of course the other idea is to keep the system the way it is. This is being promoted by companies that have already invested heavily in this “blue hat” system and have been dominating the industry and amassing huge profits as a result.

The association sympathizes with these companies, as we understand giving up a steering position in the industry is not ideal especially for shareholders. However, the simple fact is that free market forces are pushing the industry to develop and open to competition. This is not a bad thing at all as it will increase the size of the industry dramatically, encourage domestic and foreign investment, increase the development of new sales channels (i.e. health food stores), spread education to consumers, increase the number of legitimate players, which will decrease the market space for unscrupulous players seeking to cheat consumers and finally offer consumers a much larger range of healthy products to choose from. The China market is huge and there will be enough profits to go around for everyone.

In closing, the association hopes to see the light at the end of the tunnel at year’s end and looks forward to seeing Chinese regulators make the right decision by allowing market forces and consumer demand to drive legislation.

To view the association’s “Export Potential Report” [CLICK HERE](#).

To view the association’s “Industry Paper” [CLICK HERE](#).