

Questions You Should ASK

About the Food Supplements

YOU Recommend

As we go about our day-to-day routine working as educators and consultants to doctors, we are often asked similar questions about the food supplements Biotics Research Corporation manufactures, and food supplements and the industry in general. Recently, a letter was sent to Harry O. Eidenier, Jr., PhD, NMD, asking him to answer these questions. (Dr. Eidenier works as technical and clinical consultant to Viotron International, Ltd and DSD International, Ltd, both distributors for Biotics Research Corporation.)

We wish to thank Dr. Eidenier for sharing his knowledge of food supplements and the food supplement industry with the physician asking the questions and for allowing us to share this information with you.

INTRODUCTION BY DR. EIDENIER

"Thank you for taking the time to ask questions we wish every physician would ask of us regarding manufacturing procedures, who we are and what we do. As the (recent) article in Chiropractic Economics indicated, the food supplement industry is fraught with misinformation, half-truths and in some cases outright deceit. It is our hope that the information contained in this response will strengthen your faith in Biotics Research products and make you even more inclined to provide them to your patients."

We hope you find the answers to the questions that follow helpful in evaluating the food supplements you recommend to your patients.

THE FOURTEEN QUESTIONS YOU SHOULD ASK (AND ANSWER) ABOUT THE FOOD SUPPLEMENTS YOU RECOMMEND!

1) Does your food supplement supplier actually manufacture their own products and the ingredients that make up the products?

Biotics Research Corporation is a primary manufacturer; most products are produced in-house with many of the ingredients produced in-house. Many other producers would simply stop here and let you attempt to figure out what they mean by most. The simple truth, no matter what some other manufacturer may tell you is, some of the ingredients common to many products in the food supplement industry are manufactured by pharmaceutical companies. Ascorbic acid, D-alpha tocopherol, B vitamins (both the phosphorylated and hydrochloride forms), hydrochloric acid, pepsin, ammonium chloride and some amino acids, are a few of the examples. Others may

tell you "we do not do that, all of our products are natural and we do not use any synthetic vitamins, etc". We have too much respect for your intelligence to expect you to buy that bill of goods. A simple review of the label(s) of the products produced by someone who tells you this will reveal the presence of many of the nutrients mentioned above and the fact is they purchase them from pharmaceutical companies just as Biotics Research does. Then what makes Biotics Research different from everyone else? BRC (Biotics Research Corporation) purchases their raw materials, where possible from organic growers and only from manufacturers who use state of the art extraction procedures, produce in small batches and always use fresh source material. While the molecular structure of the nutrients may be the same, it is not hard to see that ascorbic acid from beets costs more than ascorbic acid from corn cobs, D-alpha tocopherol from fresh soy oil costs more than a synthetic vitamin E and inositol from rice costs more than inositol from corn. This is the whole truth. No matter what you are told by others, no company can do it all. The "ammonium chloride tree" simply does not exist.

Lastly, when we do purchase materials from an outside source, they are purchased only in small amounts and are purchased only from suppliers that provide extraction dates, source information, nutrient levels, etc. The materials are rechecked in our fully licensed and equipped laboratory and any raw material that does not equal or exceed the data provided is discarded or returned for replacement/credit. Buying in small amounts and from quality sources is expensive; but, it is just one of our commitments to providing you the "best of science and nature".

2) What does your food supplement manufacturer make or produce in-house?

The previous paragraph could leave you thinking that BRC is simply another labeling company putting things in bottles that look good on paper and hopefully work. This is not true. All of our emulsified nutrients, glandulars, vegetable cultures, special nutrients (ADP, SOD, catalase, vegetable culture minerals, etc), are produced in-house. A review of our labels will then reveal that the vast majority of what we provide the physician is produced by BRC. As indicated previously, no company can do it all in-house; however, where even remotely possible, we do extract, manufacture, etc., in-house from raw materials either grown by BRC or obtained from high quality raw material suppliers. More on this later in the response.

3) Is your food supplement manufacturer a fully licensed federally registered pharmaceutical facility?

Although they do not produce "controlled substances", BRC's license would allow them to do this. Although it is not a controlled substance, an example of a product recently introduced where a pharmaceutical license is required is "GTA". GTA is a porcine thyroid glandular concentrate processed to remove thyroxin. You ask, so what, everyone has a thyroid glandular product. This may or may not be true. The truth of the matter is, in order to lawfully purchase thyroid glands, you must have a pharmaceutical license. Without a current pharmaceutical license (according to the current federal statutes), you simply cannot purchase them, never mind concentrate them. Does everyone who produces thyroid glandular products have a license that allows them to purchase glands, or is what is being sold as thyroid simply neck material? Not everyone in the business of food supplement manufacture is dishonest; however, based upon this information, you may want to ask a few questions and see what kind of answers you receive.

4) Does your food supplement supplier manufacture in accordance with good manufacturing practices (GMPs)?

Yes. All current (and proposed) GMPs are met or exceeded by Biotics Research.

5) What is the source of the ingredients in your food supplement suppliers products, do they grow their own plants such as a competitor claims to do?

The plant material used by Biotics Research is either grown by us (sprouts) or where possible purchased from organic growers (beets, flax seed, rice, etc). A well-known food supplement manufacturer claims to grow all their plants. To a certain degree this is probably true; however, you may want to review their labels and then ask the question, do you grow mushrooms, tillandsia, all of your carrots? We are not making this statement to undermine your confidence in another vitamin line; but, if someone tells you they grow all of their plants, you may want to see how much of this is truth and how much is fiction.

6) Does every batch of tablets produced by your food supplement manufacturer go through a disintegration test?

The answer to this should be "Yes". At BRC, every batch is tested for dissolution capabilities.

7) Are chemical solvents used in the processing of the food supplements you recommend?

At BRC, the answer is "No". Hexane, chloroform and other harsh/volatile chemicals are not used. If required, only mild organic acids such as those normally produced in healthy humans are used. It will be interesting to see what happens if the proposed food labeling regulations take effect. Under the proposed guidelines, companies must list (on the label) all chemicals used in the various extraction processes they employ. Many of the companies are fighting this issue (not BRC) because they do not want the fact known that chemicals such as hexane, etc., are used to remove fat, etc., from adult glands and organs prior to the processing of the material. Biotics Research is not required to do this as the presence of fat and fibrous material is almost nonexistent on neonatal glands and organs.

8) Are any coatings used on your food supplement suppliers products?

With BRC products, the answer is "Yes". Some of the products such as those containing proteolytic enzymes and other products where both peer reviewed literature and clinical feedback indicate that dissolution of the product should not begin until well into the stomach or in the small intestine, are coated with a thin vegetable coating. This is an organic coating and will not prevent the dissolution of the product if the pH of the small intestine is not alkaline enough or the pH of the stomach is not acid enough. We do this to insure dissolution takes place in the correct place. Again, Biotics Research does not use "plastic" or inorganic coatings; only pure vegetable coating is used and then only when it is in accordance with good therapeutic principles.

9) Does your food supplement supplier use binders with their food supplement tablets?

Our answer is "Yes". Primarily, vegetable cultures are used to hold the tablets together. Whenever you see SOD and catalase at 15-20 mcg per tablet on the label, this indicates that the vegetable culture was used as the binding agent for the tablets. Some vitamins, minerals and other organic material will simply not hold together when bound with the vegetable culture. In these cases, magnesium (vegetable source), cellulose (obtained from organic sources), or rice bran, is used. Flowing agents (some organic material will not flow through the tableting or capsuling equipment without a flowing agent) are also used for some products when required. Vegetable source magnesium or rice bran is used for this procedure. This should make you wonder how some of the companies get away with telling their customers that only the pure mineral, etc., is in the capsule, etc.

10) How often does your food supplement manufacturer dismantle their equipment and clean it?

At BRC, the answer is after every batch is produced. This is one of the basic tenants of the GMPs.

11) As the batch is being made, does your food supplement manufacturer test samples for weight, hardness, shape and size requirements?

At Biotics Research, this is done on every batch.

12) Does your food supplement manufacturer keep records on every starting material and finished product to verify that a nutrient was present at the quantity listed?

Yes. Biotics Research also completes tests to insure that nutrient levels indicated on the label are equal to or exceed the level(s) indicated on the label at time of expiration. This is done by incubating the various nutrients (incubation is accepted as a viable test for simulating aging). We can assure you that in almost every product, overages of the various nutrients are placed in the products to insure the label levels are still present at the time the product expires. We also do something not every manufacturer is doing. That is, we list on our labels the level of the nutrient available, not the level of the nutrient and the carrier. For example, in order to obtain 100 mg of citrus bioflavonoid activity, we must add 200 mg of citrus bioflavonoid material to the product. Further, when we say each tablet of MG-Zyme has 100 mg of magnesium aspartate, gluconate and glycinate, we are not telling you what the level of the carrier is, we are telling you the level of the mineral present. We are probably not the only company doing this; however, this is another area you may want to investigate with other manufacturers. Unfortunately, some companies will give you the level as 100 mg of magnesium and then list the carrier and what they are doing is giving you the combination of the mineral and the carrier. In this case, the level of the mineral would obviously be lower than the amount indicated on the label.

13) Does your food supplement manufacturer encourage tours of their manufacturing facility and are educational materials available to show patients and physicians how the products are produced?

At Biotics Research, we make no secret of how we manufacture, the source of raw materials, etc. Although we have not advertised tours, etc., I can assure you that upon your request to Viotron International, we will arrange a tour of the facility and provide you with answers to any questions you may have while at the manufacturing facility. If you intend to request a tour of the facility, it can probably be done at anytime that fits your schedule. As far as educational materials for patients are concerned, we admit to being behind the power curve on this issue. Our primary concern up to now concerning literature (and it will remain our primary concern), has been to provide the physician with up to date, honest and well referenced literature on our products. We believe we have completed this mission more effectively than most of the other manufacturers. We are currently in the process of formatting patient educational material (more extensively than we have previously). At the expense of Viotron International, Ltd., a number of patient educational brochures are already available. You may obtain these by calling our office at (800) 437-1298.

14) Does your food supplement manufacturer complete in-house microbiology on raw materials for the presence of contamination, metals, micronutrient levels, etc.

Biotics Research has a fully staffed (two full time Ph.D. biochemists on the staff), licensed laboratory. We are able to and do complete all of the assays required to meet and exceed the requirements of the GMPs. It may also interest you to know that at one time (before our food supplement business was as large as it presently is and we were able to expend the time), BRC was under contract with the United States Environmental Protection Agency (EPA), to conduct the testing that was required in association with environmental disasters (Love Canal, etc).

With kind personal regards,

Harry O. Eidenier, Jr., Ph.D., N.M.D.