

Product Labeling... Buyer Beware

"Here is why expiration dates are dates that the manufacturer can guarantee product stability and 100% label compliance, and born dates can't."

What's up with the "born dates" on supplement bottles? And how does that differ from expiration dates? Not knowing the precise definitions, I asked Bill Sparks one of the principle members from Biotics Research who is intimately involved with FDA regulations and the laws surrounding labeling.

Bill has been in this industry for a long, long time. In fact many of you may not remember the "Love Canal Scandal" where back in the early 60's people were told they could build their homes on a toxic waste dump. 21,000 tons of chemicals were buried at a depth of twenty to twenty-five feet. Grass was planted and homes were built right over the dump.

Eventually some of the children started contracting unexplained illnesses, mental retardation and leukemia. Women had a high rate of miscarriages. Resisting what at that time was politically correct, the genetics team from Biotics Research Corporation volunteered to assess



the damage. They were the first team to document chromosome damage in Love Canal residents. In fact, 33% of the residents had undergone chromosomal damage. In a typical population, chromosomal damage affects 1% of people.

You can go to Wikipedia and revisit how this tragedy unfolded but my point is that the owners at Biotics Research have been doing the right thing at their own expense in our environment before it was fashionable or required by law. So when I asked Bill about the born

dates, I got a long dissertation about why they are not in the consumer's best interest. Let me give you a short version that will be very relevant to your patients.

Let's start with the term expiration dates. Expiration dates are dates that the manufacturer can guarantee product stability and 100% label compliance.

To do it correctly, a product is made and then tested for label claim accuracy. Next, the product should be re-evaluated in 6, 12, 18 and

24 months for product stability and potency.

Since most companies do not have in house phytochemistry labs, that would mean they have to send it out to another lab. Keep in mind, these are living foods that contain naturally occurring oils, proteins, enzymes, moisture and fiber. In a wet and warm environment naturally occurring bacteria may proliferate.

Another factor in product stability is how companies combine multiple ingredients in a single formula. Products may be stable individually but when you mix them together, reactions take place and stability changes.

As you can imagine, it is very time consuming and expensive to test all products in this fashion, so most companies have not made the financial commitment necessary to test their own products. Some companies may approximate expiration dates based on industry standards. But few test their own products. Unfortunately for the supplement industry, manufacturing companies are not currently required to do stability studies on their products to meet GMPs, good manufacturing practices.

So what are born dates? Born dates or "manufactured on" dates refer to some point in the production process when the product was made. The regulations surrounding born dates are very loose. It could be the beginning of the manufacturing process or at the end.

Let's use vitamin C as a specific example for clarification. The raw material supplier will give a window that the product is stable when in their original container. Two and a half years is pretty standard. Don't forget these companies have warehouses stocked with product and the clock is ticking for them as well.

So when Biotics orders vitamin C to put in one of their formulas, they have to manufacture the product in a timely fashion because of the stability cycle. If they get it in their products, assuming there are no competing products that will denature or reduce the shelf life, they have a good two years.

But here is the part that I didn't understand. Manufacturers that use "born dates" or "manufactured on" can use that same vitamin C right up to the end of its shelf life and still be compliant. In other words, the product may have vitamin C that will expire one week after it was made. Nobody knows the difference. In effect, this allows them to sell a product that is knowingly or unknowingly deteriorating. Maintaining and testing for stability is very, very costly and that's why most companies don't do it.

Selling potentially denatured products seems unethical. I didn't know powdered forms of tocopherols, unless specifically formulated, would denature in four months; how could our patients? This means that "a supplement company could boast that it is GMP compliant, but it could be filled with expired products."

So if you are looking for a way to determine if you are working with a quality manufacturer, make sure they have expiration dates. When you see the term "manufactured on" or "born date" on the label, buyer beware! The company selling that product is not willing to do the due diligence necessary to provide you and your patients the information necessary to make the best decisions.

It costs money to throw away products that are beyond the expiration date. But just like the team Bill Sparks led in Love Canal, it's just the right thing to do.

Thanks for reading this week's edition. I'll see you next Tuesday.