PBS to Air Segment on Frontline: Supplements and Safety

Tonight, January 19th at 10:00 pm Eastern

Please check your local PBS provider to confirm when Frontline will be aired

The NPA wanted to provide you with some talking points in case you get questions regarding the PBS segment.

- Supplements are designed to “supplement” the body and should be used in combination with a healthy diet and exercise to benefit a healthy lifestyle.
- Americans are often unable to obtain the diverse variety of foods they need in order to achieve optimal levels of minerals and nutrients. For example, we don’t eat enough fish to obtain the benefits of omega-3 fatty acids.
- Americans are overweight but undernourished.
- Consumers should consult their healthcare provider to determine whether supplements are right for them and which ones would add a benefit.
- Dietary supplements are regulated as a category of food by the US Food and Drug Administration (FDA).
- Dietary supplements are the only category of food to have a federal mandatory reporting requirement for serious adverse events.
- Dietary supplement quality, identity, purity, strength, potency, composition, limits on contaminants, (collectively termed Good Manufacturing Practices or GMPs), labeling and claims are regulated by FDA.
- FDA’s dietary supplement GMPs are more stringent than conventional food GMPs.
- Consumers continue to use supplements because they are safe.
- Millions of Americans, including half of all Americans, and 70+% of elderly safely use supplements on a daily basis.
- Consumers continue to use supplements despite negative press designed to castigate the industry that supplements are somehow unregulated and unsafe.

Supplements are Regulated and Safe

If supplements are not regulated by the government, then on what basis did the government take criminal action against 117 manufacturers and/or distributors companies in November 2015? The Federal Trade Commission took action against Bayer’s Phillips’ Colon Health, claiming that their claims were unsubstantiated. Bayer won in Federal District Court. Anyone selling unsafe products or drug products masquerading as dietary supplements is not going to be in business very long. FDA and FTC have tools at their disposal to regulate the industry, and they do use them to deter criminal activity.

FDA Press Release
US has the safest and most innovative dietary supplement supply in the world, which is partly due to our unique regulatory framework but also to consumer demand. The law has been strengthened over the years through the addition of the serious adverse event reporting requirement, New Dietary Ingredient provisions that require pre-market notification, and the final rule for cGMPs.

Additionally, NPA and the industry together are developing a number of initiatives to elevate quality standards. One of our goals is to define and establish "minimum certification standards" for facilities that manufacture dietary supplement ingredients. While many manufacturers are already cGMP compliant, there needs to be an established 'minimum standards' to urge manufacturers to become compliant with part 111.

Without an industry standard there are a variety of quality methods and many different levels of implementation are used. Some companies and certifiers still rely on older final-inspection techniques, while other organizations are among the most advanced in the industry. We want to ensure the baseline is consistent, so that a rising tide can truly raise all ships.

These initiatives are being developed now by industry leaders working alongside trade associations and independent certifying bodies, which will ultimately become the standard that is used for dietary supplement ingredient manufacturers.

Below is a chart showing the number of serious adverse event reports by year from FDA regulated commodities (conventional foods, drugs and dietary supplements). The data speaks for itself.

Note: Conventional food serious adverse event data does not take into account foods under the jurisdiction of USDA, which has its own adverse event reporting system. Therefore, the conventional food SAER data underestimates the actual number. Adverse event reports displayed here are NOT causal by rule of construction. Therefore, it does NOT imply that each adverse event reported was the direct result of or caused by ingestion of a particular drug or food product.

If you have any questions please contact NPA.
Natural Products Association
The Natural Products Association (NPA) is the trade association representing the entire natural products industry. We advocate for our members who supply, manufacture and sell natural ingredients or products for consumers. The Natural Products Association promotes good manufacturing practices as part of the growth and success of the industry. Founded in 1936, NPA represents over 2,000 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids. Visit www.NPAinfo.org.

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