



July 31, 2009

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA–2009–N–0166. Economically Motivated Adulteration.

The Council for Responsible Nutrition (CRN)¹ is a Washington, DC-based trade association representing the dietary supplement industry. Our members include some of the largest and most well known ingredient suppliers, manufacturers, direct sellers and retailers of dietary supplements. We share FDA’s concern regarding economically motivated adulteration (EMA) and are pleased to offer our comments to the Agency. These comments are an expansion of those provided by CRN at the public meeting organized and hosted by FDA.²

EMA is a serious and growing concern for all consumer products industries. Whether food, dietary supplement, drugs, devices, or toys, the global supply chain has made the task of sourcing and tracing raw materials exceedingly complex. The combination of key ingredients or raw materials that are in relatively high-demand but relatively low-supply has helped to fuel EMA for a whole host of consumer products. The inappropriate reliance (intentional or not) on outdated or nonspecific test methods for identity also allows EMA to go unabated. The

¹ The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug store and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. In addition to complying with a host of federal and state regulations governing dietary supplements, our 70+ manufacturer and supplier members also agree to adhere to voluntary guidelines for manufacturing, marketing and CRN’s Code of Ethics. Learn more about us at www.crnusa.org.

² FDA Public Meeting: Economically Motivated Adulteration. Wiley Auditorium, Center for Food Safety and Applied Nutrition, College Park, MD. May 1, 2009.

absence of adequate enforcement and the perception by some that there are few, if any, consequences for committing EMA is also a major contributor to this problem.

Importance of ingredient supplier qualification

For dietary supplements, high standards for manufacturing practices combined with routine and thorough facility inspections by FDA (and other) officials are key components in the battle against EMA. The dietary supplement good manufacturing practices (GMPs), promulgated in June 2007³ are now in effect for the majority of the dietary supplement industry. This comprehensive set of regulations establishes high standards for the manufacturing, packaging and holding of dietary supplements. Holding dietary supplement manufacturers to these standards through rigorous enforcement will help to ensure that consumers have access to well made, high quality, unadulterated dietary supplements. However, the GMPs, even when thoroughly implemented are not themselves adequate to defend against EMA.

As with other consumer products, the quality of dietary supplements is only as good as that of its components and one can point to of examples of ingredients or other raw materials that are spiked and/or substituted with less costly alternatives. Suppliers of dietary ingredients and other components that make up dietary supplements are not required to follow dietary supplement GMPs and instead are held to current food GMPs⁴, a far less stringent standard. While a major emphasis of the dietary supplement GMPs is recordkeeping and documentation, especially as it pertains to product specifications (both raw materials and finished products) and sourcing of raw materials, the fact that ingredient suppliers are not subject to the same standards leaves manufacturers more vulnerable to substandard quality raw materials, such as those subject to EMA.

³ 21 C.F.R. Part 111

⁴ 21 C.F.R. Part 110

Rather than hold ingredient suppliers to the same standards, the regulation places the onus on the manufacturer of the dietary supplement to assure that the quality of sourced raw materials is appropriate. The regulation states that ingredient suppliers must be “qualified” by manufacturers: “You first qualify the supplier by establishing the reliability of the supplier’s certificate of analysis through confirmation of the results of the supplier’s tests or examinations”.⁵ Despite its emphasis in the regulation and FDA’s own both private and public comments about the importance of ingredient supplier qualification, there has been little, if any information provided from the Agency as to what proper qualification means. Little is known regarding FDA inspectors’ expectations with respect to how manufacturers should qualify ingredient suppliers. While the majority of dietary supplement manufacturers are committed to the implementation of GMPs, including proper ingredient supplier qualification, some may lack the expertise and resources needed to develop and maintain a comprehensive supplier qualification program, especially without further direction from the Agency.

Whether the decision to exempt ingredient suppliers from dietary supplement GMPs in favor of a lesser standard serves as a primary driving factor behind EMA of ingredients is unclear at this time. Dietary supplement GMPs are relatively new for all stakeholders, including FDA, and its implementation and subsequent enforcement continues to be a learning process. However, inadequate ingredient supplier qualification, especially among the smaller and less experienced dietary supplement manufacturers, coupled with the fact that ingredient suppliers are not subject to the dietary supplement GMPs, can be a contributor to sustaining a climate of EMA.

Some portion of each of the introduced food safety bills introduced in this Congress has focused on supply chain security and traceability⁶. Although recently introduced legislation is

⁵ 21 C.F.R. Part 111 §111.75 Subpart E

⁶ HR 2749 – Food Safety Enhancement Act; HR 1332 – Safe Food Enforcement, Assessment, Standards and Targeting Act (Safe FEAST Act); HR 999 – Keeping America’s Food Safe Act; HR 875 – Food Safety Modernization Act; HR 841 – Protect Consumers Act; HR 815 – Safe and Fair Enforcement and Recall for Meat, Poultry and Food

aimed at conventional foods and not dietary supplements, whatever is ultimately passed by Congress will likely affect dietary supplements and is likely impose substantial additional regulatory burdens on the industry. Provisions for third party certification, fast-track import status and country of origin all point to the need to understand and maintain integrity of the supply chain. The ability to trace a potential problem or outbreak through the distribution chain is entirely dependent on whether and how well users qualify their raw material vendors. This again stresses the importance of ingredient supplier qualification.

Limitations of reliance on testing alone

It is extremely difficult and costly to follow and trace raw materials throughout the distribution chain. It is equally as challenging to be aware of, develop, disseminate and implement the necessary tools to detect economic adulterants. Even if it were economically feasible, one could not possibly test all materials at each stage of the distribution chain for all possible economic adulterants. Manufacturers face the same challenges as FDA when it comes to the awareness of an ability to test for known and potential adulterants. Analytical methods to detect specific economic adulterants may or may not be developed and available for use. In many cases, there is inadequate dissemination to and application of these methods by manufacturers to ensure their products are free of such adulterants. With the efforts of perpetrators evolving so rapidly, consumer products companies are frequently faced with new, previously unknown adulterants. Furthermore, one cannot test for adulterants that one does not know exist. Finally, one cannot “test quality into products”.

One key to avoiding economic adulteration, in the presence or absence of extensive raw material testing, is proper supplier qualification. This is essential to assure end product quality

Act; HR 814 – Tracing and Recalling Agricultural Contamination Everywhere Act; HR 759 – FDA Globalization Act; SB 893 – Imported and Domestic Product Safety Act; SB 510 – FDA Food Safety Modernization Act; SB 429 – Ending Agricultural Threats: Safeguarding America’s Food for Everyone Act; SB 425 – Food Safety and Tracking Improvement Act; SB 92 – Imported Seafood Safety Enhancement Act

and is the best and perhaps only way to avoid economic adulteration. A serious and vigilant approach to ingredient supplier qualification is now needed for all consumer products categories – no product is immune. The lack of awareness of adulterants and absence of proper methods to detect some economic adulterants further reinforces this reality.

Ingredient supplier qualification guidelines are needed for dietary supplements

To this point we have identified four realities that contribute to the current climate of EMA. Dietary ingredient suppliers are subject to the food, not dietary supplement GMPs; clear guidelines from FDA on what constitutes proper ingredient supplier qualification do not exist; new requirements to be imposed through food safety legislation have yet to be enacted; and dietary supplement manufacturers cannot rely solely on testing to thwart EMA. These all point to a need for the dietary supplement industry to develop ingredient supplier qualification guidelines.

To assist with the qualification of ingredient suppliers the dietary supplement industry developed the Standardized Information on Dietary Ingredients (SIDI™) protocol⁷. SIDI assists in the exchange of raw material information between ingredient suppliers and manufacturers. While it is an effective tool, it represents only one small component of the ingredient supplier qualification process. Additional effective tools and guidelines need to be developed to assist manufacturers with ingredient supplier qualification and to help ingredient suppliers assist their customers with proper GMP compliance.

CRN urges FDA to work collaboratively with the dietary supplement industry to develop guidelines for ingredient supplier qualification. Such guidelines could serve as the basis of industry best practice or even future regulation. There are precedents from the excipients⁸ and

⁷ <http://www.crnusa.info/SIDI/>

⁸ <http://www.ipecamericas.org>

prescription pharmaceutical⁹ industries where similar industry-FDA collaborative efforts have been undertaken. We are now looking to the Agency to work with the dietary supplement industry in a similar capacity.

Manufacturers are not exempt

Although the focus of our comments is on the importance of ingredient supplier qualification to abrogate widespread EMA, we must emphasize that the climate that contributes to EMA requires a “two-way street”. If there are willing buyers of sub-par raw materials, whose true actives are substituted with or “cut” by less expensive (and at times dangerous) materials, there will always be willing sellers. Manufacturers that knowingly accept economically adulterated raw materials, whether through failure to qualify suppliers, failure to properly identify materials by using outdated, nonspecific assays, or by just turning a blind eye, should be reprimanded by FDA. Manufacturers should know better than to accept on its face a raw material whose price is a fraction of the going rate in the marketplace. That itself should serve as a “red flag”, and be due cause for concern. FDA can only hold these companies accountable by increasing the frequency and intensity of inspections of manufacturers’ facilities. CRN joins others in echoing the need for increased FDA enforcement through inspections. Without the threat of adequate enforcement or perceived consequences for criminal behavior, the current climate of EMA will continue.

Reporting instances of EMA to FDA

CRN and its member companies recognize the need for and importance of informing FDA about known or suspected instances of EMA of dietary supplements or ingredients. We also recognize that it is not FDA’s intent to use specific examples of EMA “against” the industry

⁹ <http://www.rx-360.org/>

or any one company. We do believe, as the Agency has maintained, that FDA's broad interest is in identifying signals or patterns that may be predictive of EMA. Despite this understanding, concerns remain about FDA's recent requests for information from the industry regarding instances of EMA.¹⁰ It is uncertain exactly how FDA would use information pertaining to, for example, a specific case of EMA regarding a dietary supplement raw material reported to them by a manufacturer. Companies have legitimate concerns about retribution and liability that may accompany or result from such a notification to FDA. CRN recommends that FDA establish a system of EMA information gathering and maintenance that would alleviate such concerns. A system (perhaps web-based) that collects information anonymously would likely result in FDA receiving more information on existing or potential EMA problems. While such a system is likely to provide much less detailed information, and perhaps even erroneous leads, it can still be useful in identifying signals or areas of potential concern. It is important that if FDA were to develop such a system, that the information collection and maintenance processes be carefully controlled to avoid breaches. We recommend that this information not be made publicly available for a variety of obvious reasons, including that this would serve as a disincentive for industry members to provide sensitive information to the Agency.

EMA is a serious, and in some instances, dangerous issue. At a minimum, it undermines consumer confidence and at the extreme costs lives. We appreciate the sense of urgency shown by FDA regarding this issue and we recommend that ingredient supplier qualification be an emphasis throughout the Agency going forward. We offer our full support for an industry-FDA collaborative effort to address ingredient supplier qualification for dietary supplements.

Thank you.

Andrew Shao, PhD



¹⁰ Economically Motivated Adulteration; Public Meeting, May 1, 2009, College Park, MD; Comments from Randall Lutter, Deputy Commissioner for Policy, FDA, at the CRN Board of Directors meeting, June 4, 2009

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