



Aug 06, 2009

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

RE: Docket No. FDA–2009–N–0247. Food and Drug Administration Transparency Task Force.

Introduction

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 applaud the FDA’s effort to make useful and understandable information about FDA activities and decision making more readily available to stakeholders and are pleased to offer our comments to the Agency.

CRN and its members support the formation of a task force that will identify key initiatives to assist the agency in fostering appropriate transparency. It is our hope that recommendations that emerge from this task force will improve the FDA’s ability to interface with both the public and regulated industry and ultimately improve the Agency’s ability to

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.

protect public health. CRN agrees that transparency has become increasingly necessary as we face challenges such as globalization of the supply chain, re-emergence of economically motivated adulteration, and an intricate food distribution network that increases the complexity of recalls related to contamination.

The FDA has an important yet challenging mission to promote and protect public health. The Agency's internal decision making processes directly impact both the end-user and the producer of FDA-regulated products. It is important that the FDA's efforts to improve public access and understanding of its internal workings and decision making processes have the intended impact of supporting the overall FDA mission - promoting and improving public health. At the FDA Transparency Task Force public meeting held Tuesday June 24, 2009 in Washington D.C.², there were several well articulated examples of how disclosure of certain proprietary information or data may in fact have the opposite effect on public health. Successful research and development of FDA-regulated products is often dependent on the protection of intellectual property. If the ability to protect intellectual property is inadvertently removed through new policies aimed to increase transparency, this may reduce the incentive for innovation and hamper the economic viability of companies developing health-promoting and life saving drugs, nutritional supplements, and/or medical devices. CRN requests that each proposed change recommended by the FDA Transparency Task Force be carefully vetted for its (a) ability to improve the public's trust, health, and safety and (b) appropriately protecting confidential information.

Dietary Supplements

One vital aspect of FDA transparency relates to sharing information with the public, which is likely a primary focus of the FDA Transparency Task Force. However, a second equally important aspect relates to increasing industry representatives' understanding of the FDA's

² Docket No. FDA-2009-N-0247. Food and Drug Administration Transparency Task Force; Public Meeting. Food and Drug Administration, HHS. Webcast of Public Meeting available at: <http://wpc.0172.edgecastcdn.net/000172/fda/FDA.htm>

decision making processes. CRN and its members represent the dietary supplement industry, which is just one category of the many FDA-regulated products. CRN appreciates this opportunity to share its recommendations specific to dietary supplements, that we feel could be important components of efforts to improve transparency. In addition, these recommendations will assist CRN and its members in supporting the FDA's mission to improve public health and safety.

I. New Dietary Ingredients Notifications (NDIN) and the FDA's Decision Making Process

CRN and its members recommend additional clarity regarding the FDA's activities and decision making process for reviewing New Dietary Ingredient Notifications (NDIN). Examples where improved guidance from the FDA on NDINs is requested include:

- a) Since the passage of DSHEA, the industry has been operating under the assumption that when an entity submitted a NIDN to the Agency, and no objections were forthcoming, that ingredient may be utilized by a separate company marketing a dietary supplement containing a different formulation in the United States as long as the chemical identity of the ingredient contained in the formula was identical to that which was submitted to FDA. This assumption, correct or not, has neither been challenged nor questioned by FDA via issuance of guidance or warning letters or other form of enforcement. Recently, FDA has made public comments suggesting it is applying a different standard, requiring any firm wishing to use a permitted NDI to submit an additional notification for any new formula containing the NDI.³ While this may not represent a shift in interpretation within the Agency, it is a shift nonetheless in that FDA had never previously communicated this to industry stakeholders. CRN requests a better understanding of the evolution and basis for FDA's decision to allow the industry to operate for nearly 15 years under a set of seemingly incorrect assumptions. CRN has additional concerns

³ "Bringing New Ingredients to Market: FDA Guidance and Developments in the New Dietary Ingredient Notification Process". Webinar, presented by the Council for Responsible Nutrition and Virgo Publishing, December 10, 2008. Webinar can be accessed on demand at http://www.nutrilearn.com/ndin_webinar/

about the lack of awareness among industry members of FDA's abrupt decision to only recently communicate its interpretation of the law. FDA has not relayed what appears to be a new viewpoint adequately enough to ensure that the industry takes this seriously. We understand that resources (or lack thereof) may have played a role in these circumstances, but we also believe that a lack of transparency around FDA's decision making process to be an equal contributor.

GMP Inspections

For dietary supplements, high standards for manufacturing practices combined with routine facility inspections by FDA officials are key components to promoting and protecting the public's health. The dietary supplement good manufacturing practices (GMPs), promulgated in June 2007⁴ are now in effect for the majority of the dietary supplement industry. This comprehensive set of regulations establishes standards for the manufacturing, packaging and holding of dietary supplements. However, to date there have been relatively few FDA-GMP inspections.

The dietary supplement industry would benefit from an increased understanding of the FDA-GMP inspection process. With relatively sparse historical data on completed inspections, it is difficult for manufacturers of dietary supplements to prepare for inspections. For example, little is known regarding FDA inspectors' expectations with respect to how manufacturers should qualify ingredient suppliers or what proper qualification means. Given that dietary supplement GMP inspection process is new for everyone, including FDA inspectors, CRN requests that appropriate measures of transparency be developed to help all to better understand and prepare for the inspection process.

CRN seeks clarity from FDA on its inspectors' access to records during a GMP inspection. FDA has stated publicly that inspectors will request documentation on how manufacturers

³ 21 C.F.R. Part 111

qualify their ingredient suppliers and other vendors. Presumably, this would include the manufacturer's and/or third party auditor's audit report of ingredient suppliers' facilities. CRN has concerns about FDA access to this information. Frequently, these audit reports include confidential or proprietary information, in the form of a proprietary manufacturing process or other trade secrets. Manufacturers (and third party certifiers) are often required by their suppliers to execute and abide by a confidentiality/nondisclosure agreement (CDA). Providing FDA inspectors with unfettered access to this information could be considered a violation of such agreements, placing the manufacturing in a precarious legal position – violate the CDA, or receive citations from the inspector. FDA should resolve the situation by not requiring the manufacturer to disclose confidential information under these circumstances, and instead present a direct request to the ingredient supplier for the information. This would effectively remove the manufacturer from the difficult position of having to make such a decision.

Irrespective of how FDA decides to proceed under these circumstances, the Agency's position should be made clear to the industry so that manufacturers can be appropriately prepared for inspectors' requests.

The mandated rapid release of GMP inspection results to the public, as recommended by the Center for Science in the Public Interest during the FDA Transparency Task Force Public Meeting⁵ is an area that needs careful consideration. It is clear that FDA inspectors need access to a wide variety of information and records to properly complete the GMP inspections. However, it is not clear how this information could benefit the health of dietary supplement users. The average consumer is not likely to be able to reach any informed conclusions by reviewing a complex inspection report. However, a knowledgeable competitor may be able to access key information from these reports that could affect competition. CRN and its members believe that the issue of widespread public disclosure of GMP inspections and other potentially sensitive documentation should be closely evaluated to ensure the proper balance between increasing public safety and the unnecessary disclosure of proprietary trade secrets.

² Docket No. FDA-2009-N-0247. Food and Drug Administration Transparency Task Force; Public Meeting. Food and Drug Administration, HHS. Webcast of Public Meeting available at: <http://wpc.0172.edgecastcdn.net/000172/fda/FDA.htm>

Transparency of the Supply Chain

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 GMPs⁶. The dietary supplement GMPs place responsibility 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”.⁷ Proper ingredient supplier qualification is not only vital for GMP compliance; it also helps to maintain the integrity of the supply chain, which has been an emphasis of recently introduced food safety legislation.⁸ To date there has been little, if any specific information provided from the Agency as to what proper qualification means.

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.

Implementation and Enforcement

As part of the FDA Transparency Task Force public comment process, the Agency has received comments that suggest, in order for FDA transparency to be impactful, first there

⁶ 21 C.F.R. Part 110

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

⁸ 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 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

needs to be a restoration of trust among the public with regard to the FDA.⁹ CRN and its members have long been supportive of policies and regulations that have set high standards for dietary supplements, including dietary supplement GMPs, mandatory serious adverse event reporting legislation, and efforts to increase resources allocated to FDA. These policies inherently are designed to increase the trust of the public with regard to dietary supplements. CRN recognizes that public trust in the FDA and the products it regulates is an important prerequisite for achieving the goals of the FDA Transparency Task Force.

Widespread attainment of the high standards set forth by FDA regulations of dietary supplements requires a “two-way street”. The industry must embrace the standards, while the FDA must enforce them. If there continues to be a perception of minimal consequences to non-compliance with existing dietary supplement regulations, there will continue to be “bad actors” willing to break the law. Without these companies being held accountable the opportunity exists to produce sub-par (and at times dangerous) dietary supplements, with no concern for retribution. FDA can 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, there are no perceived consequences for criminal behavior.

Industry members that have dedicated significant resources to be compliant with FDA regulations are confused and disappointed by the lack of enforcement action when egregious violations have occurred. For example in cases of dietary supplements adulterated with prescription drugs,¹⁰ which clearly threatens public health, it is both concerning and unclear why FDA has not imposed strict criminal penalties. In these cases sending warning letters to the

⁹ FDA Transparency Blog available at: <http://fdatransparencyblog.fda.gov/2009/06/the-transparency-task-forces-fourth-question.html#comments>

¹⁰ FDA new release available at : <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm109071.htm>

offenders does not send a strong enough message to those responsible, the public, or the industry that those who are commit such acts will be appropriately punished.

CRN and its members recommend to the Transparency Task Force that FDA produce clearer guidelines to FDA enforcement policies and enforcement decisions. We feel a better understanding of the potential consequences may better serve to deter potential criminal activity. In addition, when the Agency chooses a particular enforcement action (warning letter, fines, or criminal penalties) an explanation of how the FDA guidelines on were applied to reach a particular enforcement decision will give all stakeholders a better understanding of the consequences. Increased transparency of FDA policy on enforcement activities and decisions will serve to deter potential violators of FDA policies and increase public trust in the FDA and FDA-regulated products.

We appreciate the opportunity to make the above recommendations and look forward to the outcomes of the FDA transparency Task Force.

Thank you.

Douglas MacKay, ND

A handwritten signature in black ink, appearing to read "D. MacKay", with a checkmark-like flourish at the end.

Vice President
Scientific & Regulatory Affairs
Council for responsible Nutrition