



October 24, 2007

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

RE: Docket No. 2007N-0186, CFSAN 200736. Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.

The Council for Responsible Nutrition (CRN) appreciates the opportunity to provide FDA with comments regarding the Good Manufacturing Practices (GMP) Interim Final Rule (IFR): *Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients*. For the record, CRN strongly opposes this provision of the GMP final rule as presently written, and believes that it should be stricken entirely from the regulation. We believe the IFR weakens the overall system of process controls otherwise required for dietary supplements and potentially undermines a key safeguard to the assurance of product quality. However, because this rule is, for all intents and purposes final, elimination of this rule seems unlikely to occur. Therefore, having stated our opposition to the rule, we will provide specific comments below supporting our position and providing FDA with constructive input that we believe will improve the rule, assuming it moves forward.

CRN appreciates the fact that through the IFR FDA is attempting to reduce some of the costs associated with the GMPs while also “rewarding” those manufacturers of dietary supplements who routinely perform due diligence with their manufacturing process by allowing for some degree of reduced testing. However, the IFR, as presently written, accomplishes neither.

FDA’s cost estimate of the petition process (roughly \$2900) is, according to our analysis, a substantial underestimate of the true costs that would be involved. Further, the Agency’s estimate of the cost of a single identity test (\$60) is likely to be an over estimate. Nonetheless, even if FDA’s estimates are correct, according to our analysis manufacturers would have to receive about 50 lots per year of a given ingredient from a given ingredient supplier in order to simply break even on the costs associated with the petition process. According to one of our

member companies, a large manufacturer is likely to receive less than 50 lots per year for more than 90% of their incoming dietary ingredients. Smaller manufacturers (i.e. those that may benefit the most from reduced testing costs) are likely to have even fewer shipments of a given dietary ingredient, and they are less likely to have the means to file a petition with the Agency in the first place. In short, there is very little economic incentive, if any, for companies to partake in the petition process and ultimately benefit economically from reduced identity testing.

Economics aside, the purpose of the GMPs is to ensure the quality and safety of dietary supplement products for consumers. The simple and relatively cost effective identity test for most dietary ingredients is an essential part of this process, and in our opinion, the IFR undermines this by providing a potential window for errors. Indeed, an informal survey of our member companies has revealed that with the exception of a few vertically integrated companies (i.e. those that supply their own ingredients that make up their finished products), manufacturers of dietary supplements oppose this regulation, and even if/when the opportunity for reduced identity testing were to present itself, companies would not partake. They consider the identity test to be absolutely critical to ensuring the proper composition of the dietary supplement product.

As an example, we call the Agency's attention to the famous case a decade ago of products containing raw material labeled as plantain which actually contained the potent heart stimulant *Digitalis lanata*. That material apparently was never tested for identity along the supply chain. Indeed in the 2003 GMP Proposed Rule FDA points to this very example as a reason for identity testing: "The proposed CGMP regulations, had they been in effect, would have required identity and purity tests of dietary ingredients and dietary supplements and would likely have prevented the use of the *D. lanata* in these dietary supplements." No matter how well qualified a given ingredient supplier may be, or how strict the requirements may be for an exemption from 100% identity testing, such incidents can happen. In general, manufacturers are not willing to reduce identity testing of incoming dietary ingredients because the safety and liability risks are simply too great to entertain this approach and offset any potential cost savings.

However, if FDA continues to move forward with this regulation, the Agency must allow or even require more participation from ingredient suppliers in the petition process than is currently outlined. Quality-focused ingredient suppliers know their products better than anyone, and they should play a critical support role in their customers' petition process. Use of a Dietary

Ingredient Master File (DIMF) concept is one way to allow quality-focused ingredient suppliers to provide their customers and FDA with critical information pertinent to a reduced identity testing petition. Taking this approach could save significant resources, and to the extent that cost savings associated with reduced testing are significant, would lead to more loyalty to quality-focused ingredient suppliers.

The purpose of GMPs is to ensure the quality and safety of dietary supplement products. Therefore, anything that falls outside this purview should be eliminated from the regulation. The possibility of reduced identity testing represents unacceptable risks to the safety and quality of dietary supplement products. FDA's clearly stated mission is to protect the health of the American public. Therefore, it is incumbent upon the Agency to eliminate this provision from the GMP final rule. Furthermore, as currently written, the IFR provides neither an economic incentive nor any other kind of reward to quality-focused companies or consumers.

Once again, CRN appreciates the opportunity to comment on this regulation. We hope the Agency finds these comments both supportive and constructive and that they will be given ample consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Andrew Shao', with a long horizontal flourish extending to the right.

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