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CRN RESPONDS TO GAO REPORT ON DIETARY SUPPLEMENTS

WASHINGTON, D.C., March 2, 2009 — *In response to the U.S. Government Accountability Office (GAO) Report on the Oversight and Regulation of Dietary Supplements, the Council for Responsible Nutrition (CRN), the leading trade association representing the dietary supplement industry, issued the following statement.*

Statement from Steve Mister, president and CEO, CRN:

“As industry report cards go, we are pleased to see that this one demonstrates that the industry has come a long way since the original 2000 GAO report on dietary supplements was released. We are gratified that [this latest report](#) recognizes that dietary supplements are extensively regulated by the Food and Drug Administration (FDA). We are also appreciative that the report refers to several of the regulatory improvements instituted—and fought for by responsible industry—including the issuance by FDA of Good Manufacturing Practices (GMPs) specific to dietary supplements and passage of a law mandating that serious adverse events are reported to FDA. These kinds of improvements in industry regulation are the cornerstone of producing safe, high-quality dietary supplements used by more than 150 million Americans each year.

There are some recommendations in the report that CRN agrees could further strengthen FDA’s ability to protect consumers and bolster their confidence in these products. Most importantly, we agree with the report that FDA needs additional resources. We strongly believe, however, that these resources—including Agency staff time and funding—should be focused on enforcing the current laws and regulations to help ensure that all companies demonstrate a commitment to protecting consumers and producing beneficial supplement products. CRN welcomes guidance from FDA on New Dietary Ingredients (NDI); in fact we’ve called on the Agency to be more transparent and issue this NDI guidance. The industry could potentially support registration of products assuming the details are not inappropriately burdensome and would not prevent beneficial products from being brought to market. But regulations are only as strong as enforcement, and it is time for FDA to focus its energy and resources on inspections and enforcement actions directed at the small minority of companies that are giving those in the majority a black eye.

We disagree with the logic behind the recommendation of submitting all adverse event reports, versus the important need to submit serious adverse event reports. The Agency is already overburdened and understaffed, and we are opposed to creating more bureaucratic paperwork that would not result in true benefits for consumer safety. The adverse event reporting law was carefully considered and supported by numerous stakeholders, including consumer groups, and there is no need to revise a law that only recently went into effect and appears to be working.

CRN was interviewed by the GAO for this report and we will continue to work with the industry, with Congress, and with FDA and the Federal Trade Commission to help ensure consumers can be confident in the safety and benefits of dietary supplements and that they are educated on the role that dietary supplements play in a healthy lifestyle.”

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Note to Editor: The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement manufacturers and ingredient suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements, CRN members also agree to adhere to voluntary guidelines for manufacturing, marketing and CRN’s Code of Ethics. Visit www.crnusa.org.