



April 15, 2008

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

RE: [Docket No. FDA-2008-N-0077] Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program (February 15, 2008).

To Whom It May Concern:

The Council for Responsible Nutrition (CRN) and other dietary supplement associations were strong supporters of the legislation leading to the Dietary Supplement and Nonprescription Drug Consumer Protection Act which requires the reporting of serious adverse events for dietary supplements and nonprescription, or OTC, medicines marketed without an approved application received by the manufacturer, packer, or distributor to FDA. Our support stems from our long held belief that mandatory reporting of serious adverse events provides consumers with additional assurance of the safety of these products and enhances FDA's ability to ensure the public health.

On February 15, 2008 FDA published in the Federal Register a Notice soliciting comments on MedWatch Forms 3500 and 3500A (forms for reporting adverse events and other problems associated with FDA-regulated products). The Agency indicated that it has made proposed modifications to the two forms; however, no specific details were provided. CRN will use this opportunity to submit comments to FDA on possible improvements to the mandatory (3500A) MedWatch form.

CRN was pleased to see the announcement of a memorandum of understanding (MOU) between FDA and the National Institutes of Health (NIH) that established the terms of a collaboration to develop a unified Federal approach to adverse event reporting (February 6, 2008. Memorandum of Understanding Between the Food and Drug Administration and the National Institutes of Health. [FR Doc. 08-00496]

<http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-N-0043-M.pdf>). Specifically, we are pleased to see addressed the need for a Federal web-based portal through which adverse events can be easily and efficiently submitted. This is perhaps the most important advancement for adverse event reporting; it will ease the reporting burden for both the industry and FDA and indirectly benefit consumers.

Regarding FDA's estimated annual reporting burden, the information provided seems oddly outdated. The Notice clearly acknowledges the passage of the Act, yet the estimated reporting burden is listed as zero for form 3500A (Table 1 of the Notice). While it may not be possible to establish an accurate estimate of hours for reporting of serious adverse events associated with dietary supplements at this early stage and given the impending transition from hard copy to electronic format, the burden is most certainly more than zero. We request FDA revisit Table 1 of the Notice and provide a revised number for reporting burden that is more commensurate with the Agency's expectations for serious adverse event reports associated with dietary supplements. Our member companies estimate that the process takes between 30 minutes to one hour to complete, route for approval and submit the form.

The following are specific suggestions we would like FDA to consider regarding the mandatory MedWatch form 3500A.

Section C

This section is intended to provide information on the suspect product or products involved in the adverse event. Given that submission of form 3500A will soon be required by electronic means and space will likely become less of a concern, we propose that more space be allocated to list "suspect products." Many consumers practice "poly supplementation" (and/or "poly medication"); any and all products associated with or expected to be associated with a serious adverse event should be included in this section of the form; the present amount of space allotted on the current 3500A form will, in many cases, be inadequate.

Section E

This section is intended to provide information (including contact information) of the initial reporter of the serious adverse event (e.g. consumer, patient or healthcare professional). In many cases, serious adverse events related to dietary supplements are reported to dietary supplement

companies directly from the consumer. In order to preserve the privacy of the patient, we propose that FDA modify this section to allow for the use of a unique reporter identifier as a substitute for the name and address of the initial reporter, when the reporter is believed to be the patient.

Section G 7

This section intended to provide the type of report. Absent from the present list is a report that applies to dietary supplements (the 15-day report applies to an ANDA/NDA drug or biologic, but does not apply to a dietary supplement). According to the Act, “serious adverse event reports must be submitted to FDA no later than 15 business days after the report is received by the responsible person.” This requirement is distinct from “15 days,” and we request FDA make this distinction in the 3500A form.

Other

Irrespective of Federal adverse event reporting requirements, most, if not all manufacturers of dietary supplements will attempt to conduct their own investigation of the circumstances behind an adverse event reported to be linked in some manner to their product(s). This process is particularly resource intensive, especially when information pertaining to the original case report is incomplete or insufficient to enable the manufacturer to conduct its own investigation.

Therefore, we ask FDA to consider the inclusion, on both the 3500 and 3500A forms, of a disclaimer by the consumer authorizing the treating physician to speak with trained company representatives (i.e. medical officer, physician, nurse, etc...) that contact the treating physician of the patient who allegedly experienced the serious adverse event in order to obtain more detailed information related to the adverse event. Such a disclaimer would be accompanied by a “check box,” which a company’s customer service or complaint representative (i.e. the person fielding the report from a reporter) could mark after soliciting permission, verbally or in written form, from the reporter (either the physician or patient).

Finally, in light of FDA’s intended transition to an electronic or web-based submission system, we suggest that provisions be made to allow for the inclusion of attachments that may be submitted with the serious adverse event report.

CRN appreciates the opportunity to comment on this Notice provided by FDA. We hope the Agency finds these comments helpful and constructive.

Sincerely,

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

Andrew Shao, Ph.D.

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