Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal

0910-0645

JUSTIFICATION MEMORANDUM FOR 83-C CHANGE REQUEST

Consistent with the Terms of Clearance set forth in the Notice of Action dated September 3, 2009, the Food and Drug Administration (FDA or we) is submitting this nonmaterial/non-substantive change request (83-C) to obtain Office of Management and Budget (OMB) approval of two rational questionnaires used for submitting adverse event reports for dietary supplements (one rational questionnaire is for mandatory reports, the other is for voluntary reports). For the purposes of this 83-C request, there is no change to the information currently being requested; we are seeking to make available the option to submit the same information via electronic means. This request is being made so that IT development work may continue while FDA follows the process required by OMB's regulations at 5 CFR 1320.8(d) and 1320.10 to obtain approval of two proposed new questions on each of the two questionnaires and move burden hours from the information collection approved under OMB Control Number 0910-0291 to this collection approved under OMB Control Number 0910-0645.

Currently, mandatory dietary supplement adverse event reports are submitted to FDA on Form FDA 3500A and voluntary reports are submitted on Form FDA 3500. Forms FDA 3500 and 3500A are available as fillable pdf forms. In the past, FDA has not been able to receive these reports electronically but has now developed rational questionnaires by which dietary supplement adverse event information submitted on Forms FDA 3500 and 3500A may be electronically submitted to the agency via the FDA Safety Reporting Portal (the SRP). We seek OMB approval of the new rational questionnaires to the extent that they obtain the same information currently being obtained on Forms FDA 3500 and 3500A.

Although we expect the majority of respondents (75%) to make use of the electronic submission option when the system is made available to the public in late FY 13, respondents will still be permitted to submit their information using the original paper forms (Forms FDA 3500 and 3500A). FDA will decrease the estimated number of respondents submitting paper mandatory and voluntary dietary supplement reports in the 0910-0291 collection to 25% of previous levels and, correspondingly, will increase the estimated number of respondents submitting electronic mandatory and voluntary dietary supplement reports in the 0910-0645 collection to reflect our estimate that 75% of submissions will be submitted electronically.

The option for electronic submission is expected to reduce the time burden for mandatory dietary supplement adverse event reports submitters. The 0910-0291 collection estimated the average burden per response for a voluntary submitter to be 0.6 hours and the average burden per response for a mandatory submitter to be 2 hours. While we expect that a voluntary submitter will continue to take approximately 0.6 hours to submit a dietary supplement adverse event report on the electronic system (due to their infrequent need to submit a report), in contrast, we expect that the average burden per response for a mandatory submitter on the electronic system

will be 1 hour, down from 2 hours. We expect that mandatory reporters will establish an account and develop a familiarity with the system and thus be able to use its time-saving features (e.g., some contact and address information will auto-fill; text may be copied and pasted from other documents; prior submissions may be electronically accessed for review and submission of follow up information).

Plan to obtain OMB approval of proposed new questions on the rational questionnaire:
The rational questionnaire versions of the mandatory and voluntary dietary supplement adverse event report forms contain "draft" versions of two new questions. The text of the two new questions is provided below in table form. The two new questions have been marked "draft" on the screenshots submitted with this 83-C request, for ease of reference.

Table 1. -- New questions on the *mandatory* dietary supplement adverse event report	
Text of new question	**Is response mandatory or voluntary?**
In the Contact Information section, we propose to add, "Please provide contact information for you, the person who is filling out this report."	Voluntary, and only displayed if the person filling out the report is reporting on behalf of a responsible person, such as a contractor, and has not created an account on the SRP.
In the Affected Individual Information section, we currently receive the individual's weight, we propose to add a field requesting, "Height."	Voluntary.

Table 2. -- New questions on the *voluntary* dietary supplement adverse event report	
Text of new question	**Is response mandatory or voluntary?**
In the Affected Individual Information section, we currently receive the individual's weight, we propose to add a field requesting, "Height."	Voluntary.
In the Product Information section, we propose to request the ingredients of the suspect and concomitant product(s), as provided on the label of the product(s).	Voluntary.

FDA will follow the process required by OMB's regulations at 5 CFR 1320.8(d) and 1320.10 to obtain OMB approval of these proposed new questions. In its request, FDA will show the increase in the estimated number of respondents submitting electronic mandatory and voluntary dietary supplement reports to reflect our estimate that 75% of submissions will be submitted electronically. Thereafter, we will revise the estimate for 0910-0291 to account for the expected reduction in burden as manufacturers move from paper submission to electronic submission.