

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 a second version of a rational questionnaire to be used on the FDA Safety Reporting Portal (the SRP) for voluntary animal food/feed adverse event reporting. The first rational questionnaire for animal food/feed adverse event reporting was written with descriptive language specific to “pet” food. The second rational questionnaire is written with descriptive language specific to “livestock” food. For the purposes of this 83-C request, there is no change to the information currently being requested; we are seeking to make available to submitters who choose to make voluntary adverse event reports a questionnaire written in a manner that is inclusive of all animal food/feed uses.

Currently, reporters may voluntarily choose to electronically submit adverse event reports about animal food/feed via the Safety Reporting Portal. With the new questionnaire, respondents will be permitted to select whether to characterize their adverse event report as relating to “pet” food or “livestock” food. FDA expects that this characterization will not cause any change in the estimated number of respondents submitting voluntary animal food/feed adverse event reports.

The electronic adverse event report data entry screens are the same:

- Introduction
- Contact Information
 - Reporter
 - Owner
- Problem Summary
 - Affected animal information
 - Medical history
 - Problem description
- Products
 - Product details
 - How product was used
 - Product purchase location
- Contact Information for Professional (termed “Consultant” or “Veterinarian”)
- Attachments

We request OMB approval of the new rational questionnaire that uses descriptive language specific to “livestock” food as a "non-substantive, non-material" change.