Field Alert Report - Form FDA 3331
(Currently approved under OMB Control Number 0910-0001)

CHANGE REQUEST (83-C)
Date: July 16, 2014

We are proposing changes to Form FDA 3331. This form is available for paper-based submissions, and as an automated form that has XML activation and functionality with a submit button that generates an email to send the form to FDA in XML format.

We are requesting the following revisions to the reporting section at the bottom of the form:

1. A field would be added for the applicant to report their FEI or DUNS number. This number is already known to the firm.

2. A field would be added for the applicant to report a contact email address. This information is already known to the firm.

We are also requesting layout changes to existing fields within the form. For example, Field 1 "NDA/ANDA number" will be Field 3 in the revised form. Field 5 "Firm name and Address where the problem occurred" will be Field 1 in the revised form.

We are also requesting functionality changes to the fields on the automated version of the form to enable expansion of the fields as information is added by the applicant.

We currently have OMB approval for 8 hours for applicants to prepare and submit this form to FDA (0910-0001). The additional time resulting from these proposed revisions (i.e., adding the DUNS or FEI number and an email address) would be approximately one minute. In addition, any additional time that may be needed for applicants to become familiar with the layout and functionality changes will be offset by the savings in time because applicants will no longer have to prepare and submit attachments to the form.