

## NON-SUBSTANTIVE JUSTIFICATION (83-C)

OMB Control Number 0910-0458

Biological Products: Reporting of Biological Product Deviations in Manufacturing;  
Forms 3486 and 3486A

The changes/redesign for Form FDA 3486 include the following:

- The Distribution, Notification, and Additional Information fields have been moved to the same row as the other fields (Unit #, Collection Date, and Expiration Date). All fields now appear on one row rather than three rows.
- The Row # field was added so the information can be entered on one screen rather than entered on separate screens.
- The Import Button was added above the fields so that saved data can be imported electronically rather than entered manually (See also second bullet above entry fields/buttons).

The changes/redesign for Form FDA 3486A include the following:

- The Multiple Selected Row field was added to enable entry of the same value to multiple rows rather than to individual rows.
- The Row # and Unit # fields were added. The unit # is automatically populated from Form FDA 3486.
- The Domestic and Foreign field dropdown menu and Distribution Pattern field were combined into one field (the dropdown menu is now under the Distribution Pattern column heading).
- # of Other field was deleted from the list of fields under the Provide Counts Related to Distribution Pattern heading.