

**“General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, Forms FDA 356h and 2567”**

**(OMB Control Number 0910-0338)**

**CHANGE REQUEST (83-C)**

**Date: February 28, 2014**

In brief, we are proposing a change to FDA Form # 356h. The only update to this form since OMB’s approval in mid-January, has been the addition of the following:

Field 29 – Establishment contact information:

- ‘Country’ in Establishment Contact Information – *this is a single text box; some establishment contacts are not in the US, so the country text box allows them to provide the information where the contact is located.*
- ‘N/A’ for ‘Is the site ready for inspection?’ – *this is a selection box to check/uncheck; for establishments with a status of inactive or withdrawn, the ‘N/A’ box would be applicable.*

Since the release in November 2012, we soon realized that we needed this on the form. The burden of time is minimal, and combined is less than a minute at most.

We hope to release the revised form in March.