

Food and Drug Administration  
Non-Substantive (editorial) Change Request  
OMB Control No. 0910-0338

**Purpose:** FDA is requesting a non-substantive (editorial) change to Form FDA 356h, *General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, Form FDA 356h*, currently approved under OMB Control No. 0910-0338.

**Background:** Regulations in 21 CFR Parts 314 (Applications for FDA Approval to Market a New Drug) and 601 (Biologics/Licensing) govern the submission of new drug applications and biologics, respectively. FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) review these submissions, where the agency has developed Form FDA 356h to assist respondents in this regard. The application form serves primarily as a checklist for firms to gather and submit certain information to FDA. As such, the form helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. In addition, the form provides key information to FDA for efficient handling and distribution to the appropriate staff for review. The form is available electronically and may be submitted electronically.

There are no additions, deletions or any substantive changes to this form. This is an editorial change wherein Fields that were mis-numbered in previous version have been correctly numbered in this version. The correctly numbered fields are now Fields 30-38. They were previously mis-numbered as Fields 31-39.

We hope to release the revised form on May 1, 2018.