

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

Purpose: FDA is requesting non-substantive change approval of Form FDA 356h, *Application to Market a New or Abbreviated New Drug or Biologic for Human Use*, 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 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.

Justification: We believe these revisions will facilitate more expeditious processing as they allow respondents to provide greater specificity regarding the submission. Specifically:

Field 20: language update – added ‘s’ to Drug, Number and Product

Field 24 (new language and design) – ‘Human Factors Information’:

24. Does this submission contain:		
<table style="width: 100%; border: none;"><tr><td style="border: none; padding: 0 10px;"><i>Only Pediatric data?</i> <input type="checkbox"/> Yes <input type="checkbox"/> No</td><td style="border: none; padding: 0 10px;">Human Factors information? <input type="checkbox"/> Yes <input type="checkbox"/> No</td></tr></table>	<i>Only Pediatric data?</i> <input type="checkbox"/> Yes <input type="checkbox"/> No	Human Factors information? <input type="checkbox"/> Yes <input type="checkbox"/> No
<i>Only Pediatric data?</i> <input type="checkbox"/> Yes <input type="checkbox"/> No	Human Factors information? <input type="checkbox"/> Yes <input type="checkbox"/> No	

Field 27 & 28: Fields will be removed. Consequent fields will be renumbered.

Field 29 (new field 27): The second portion of field 29, the heading needs to be more specific by adding the following bolded words: **Establishment Contact Information at the site/facility**

Field 31 (new field 29, box 18): MDUFMA should read ‘MDUFA.’

Bottom right hand corner of page 2: Item 31 has been updated to Item 29