**Records and Reports Concerning Experience with Approved New Animal Drugs**

**OMB Control No. 0910-0284**

**JUSTIFICATION MEMORANDUM FOR 83-C CHANGE REQUEST**

The Food and Drug Administration (FDA or we) is submitting this nonmaterial/non-substantive change request (83-C) to obtain Office of Management and Budget (OMB) approval of the electronic submission version of existing Form FDA 2301, which is currently approved under OMB Control Number 0910-0284. There is no change to the information previously requested; we are seeking to make available the option to submit the same information via electronic means.

Section 514.80 of our regulations (21 CFR 514.80) requires applicants to keep records of and report to us data, studies, and other information concerning experience with new animal drugs for each approved NADA and ANADA. Form FDA 2301 is used to submit the required periodic reports (§ 514.80(b)(4)); special drug experience reports (§ 514.80(b)(5)(i)); promotional material for new animal drugs (§ 514.80(b)(5)(ii)); and, distributor statements (§ 514.80(b)(5)(iii)).

Currently, Form FDA 2301 is available as a fillable pdf form. FDA has now developed a method by which information concerning experience with new animal drugs submitted on Form FDA 2301 may be electronically submitted to the agency via eSubmitter. We request OMB approval of the new electronic Form FDA 2301 as a "non-substantive, non-material" change.

Based on our experience with recent adoption of electronically submitted forms, we expect the majority of respondents to make use of the electronic submission option when the system is made available to the public in July 2017. However, respondents will still be permitted to submit their information using the original Form FDA 2301 fillable pdf form.