U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine

Electronic Submissions System Broadcast Message

October 7, 2016

Introduction

This is an update on the latest news concerning CVM's Electronic Submission System (ESS) Program to industry stakeholders. This broadcast contains very important information on the following subject(s):

- CVM/ONADE eSubmitter Policy Enforcement

CVM ONADE Policy for the Completion of eSubmitter Submissions

Effective November 1, 2016, FDA/CVM/ONADE will expect all eSubmitter submissions to be filled out with complete, accurate and consistent information. The eSubmitter template is considered the authoritative source for all submitted information. All questions that are categorized as a required field (designated with a blue dot in the templates), must contain complete and accurate information that is consistent with any supporting documents attached to the submission. Failure to meet these standards may result in a refuse to review or refuse to file action.

When sponsors do not answer the template questions it nullifies the benefit of having a standardized template for reviewers. The purpose of this standardization is to structure all the necessary information in a consistent manner to facilitate an efficient review process. Using "see attached" is not acceptable as an answer as it forces the reviewer to search for the necessary information, which is a time burden. There are situations where "see attached" IS necessary. These are unique cases where the structure of the template questions does not permit accurate information. These situations should be rare and the sponsor should contact ONADE prior to submitting.

Additional information about CVM eSubmitter program can be found on our website, http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm226814.htm.