Pilot Participants: How to Submit Nonclinical Data as Part of the CVM SEND Pilot Program (CVM SEND Pilot; Notice of Pilot Project [Docket No. FR-2009-N-0561]

Background:

This pilot project aims to test the ability of Standard for Exchange of Nonclinical Data (SEND), a new electronic data standard format, to support the review of margin of safety and nonclinical toxicology study data submitted to INAD files and as part of NADA's at CVM as part of the human food safety and target animal safety evaluations.

Instructions

Submit PDF study reports along with SEND Datasets to CVM either by post as a compact disc or electronic-mail (depending on the size). The participants may also use any private or public courier service. When sending information, do not refer to any submission numbers or INAD codes on the outside of the mailing.

1. Submit the test SEND datasets and any accompanying materials as a compact disc by post. The envelope in which the materials are sent should be addressed to:
    Attn: Angelica Moreno
    Re: CVM SEND Pilot Project
    Center for Veterinary Medicine, HFV-120
    7500 Standish Place
    Rockville, MD 20855

2. Immediately email the following individuals to alert them that dataset has been sent and the method of arrival:

Angelica Moreno: angelica.moreno@fda.hhs.gov
Amey Adams: amey.adams@fda.hhs.gov
Kimon Kanelakis: kimon.kanelakis@fda.hhs.gov
Janis Messenheimer: janis.messenheimer@fda.hhs.gov
Veronica Taylor: veronica.taylor@fda.hhs.gov

In the email, include the number and types of studies that are being submitted. CVM will respond by email once the material is received. The CVM SEND pilot project team will validate the datasets. CVM will communicate with the pilot participants on the outcome of the validation process. If the datasets fail validation, a validation report will be forwarded to the pilot participant. Both data formats (i.e., PDF and SEND) will be used

by FDA for pilot evaluation purposes and will be placed in a secure, restricted database behind the FDA firewall and only available to FDA employees evaluating the CVM SEND Pilot Program.

Datasets provided for the pilot project will not be processed by the Document Control Unit, and will not be filed as a submission. Upon conclusion of the pilot, all datasets submitted for the pilot will be destroyed.