

**BASIC INFORMATION REGARDING SUBMISSION OF NOTICES OF CLAIMED  
INVESTIGATIONAL EXEMPTION TO THE CENTER FOR VETERINARY  
MEDICINE**

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On March 20, 1997, the Agency published the Electronic Records; Electronic Signature regulation (21 CFR Part 11), which provides for the voluntary submission of parts or all of an application, as defined in the relevant regulations, in electronic format without an accompanying paper copy.

The Center for Veterinary Medicine (CVM) has a procedure which allows participating sponsor companies to submit Notices of Claimed Investigational Exemption (NCIEs), often referred to as drug shipment notices required under 21 CFR 511.1, as e-mail attachments via the Internet.

All submissions should be addressed to:

Center for Veterinary Medicine  
Food and Drug Administration  
7500 Standish Place  
Rockville, MD 20855  
(E-mail: [cvmdcu@bangate.fda.gov](mailto:cvmdcu@bangate.fda.gov))

Applicants should consult with the Office of New Animal Drug Evaluation, CVM for details on how to proceed with electronic submission of information (e.g., method of transmission, media, file formats, technical protocols, etc.). Additionally, an electronic version of the guidance document explaining procedures for electronic submission of NCIEs is available on the CVM Home Page on the Internet (<http://www.fda.gov/cvm/>), or you may obtain a paper copy by calling CVM'S Communications Staff at (301) 594-1755.

Questions regarding electronic submissions of NCIEs and the guidance document maybe submitted to the Project Coordinator, Dr. Charles Andres, Center for Veterinary Medicine, HFV-1 28,7500 Standish Place, Rockville, MD 20855, or via e-mail to [candres@bangate.fda.gov](mailto:candres@bangate.fda.gov), or phone at (301 ) 827-7561.

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