

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

DOCKET NO. 92S-0251

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.

To determine the practicality of electronic submission and review as an alternative to current paper-based process, the Center for Veterinary Medicine (CVM) has proposed a pilot project which will allow participating sponsor companies to submit Notices of Claimed Investigational Exemption (NCIE), often referred to as drug shipment notices required under 21 CFR 511.1, as an e-mail attachment via the Internet.

All submissions should be addressed to:

Center for Veterinary Medicine (HFV-120)
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855
(E-mail: cvmdcu@bangate.fda.gov)

Applicants should consult with CVM for details on how to proceed with the electronic submission (e.g., method of transmission, media, file formats, technical protocols, etc.). Additionally, an electronic version of the guidance document for this pilot project is available on the CVM Home Page on the Internet (<http://www.cvm.fda.gov>), or by calling CVM's Communications Staff at (301) 594-1755.

Questions regarding the pilot project and guidance document may be submitted to Dr. Charles Andres, Center for Veterinary Medicine, HFV-128, 7500 Standish Place, Rockville, MD 20855, or via e-mail: candres@bangate.fda.gov, or phone at (301) 594-2604.

SEPTEMBER 4, 1997