

Associate Director, Policy and Regulation (HFV-6)

Electronic Submission Pilot Project Extension
Notice of Claimed Investigational Exemption (NCIE)

Dockets Management Branch (HFA-305)

We request that you place the attached in Docket 92S-0251.

G.A. Mitchell, D.V.M.

Attachment

**BASIC INFORMATION REGARDING SUBMISSION OF NOTICES OF CLAIMED
INVESTIGATION EXEMPTION (NCIE) TO CENTER OF VETERINARY MEDICINE**

DOCKET NO. 92S-0251

On September 4, 1997, the Center for Veterinary Medicine (CVM), placed in the referenced docket a proposal to conduct a pilot project to determine the practicality of electronic submission and review as an alternative to the current paper-based process of submitting Notices of Claimed Investigational Exemption (NCIE) required by 21 CFR 511.1.

The pilot project is being extended to March 8, 1999.

All instructions for submission, to include addresses and contacts, remain as stated in the September 4, 1997 docket notice. The CVM standardized NCIE form, Form FDA 3458 (1/98), may be submitted via either electronic transmission or hard copy. The form 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.

March (insert date of placement in docket), 1998