DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DATE: May 25, 2001

FROM: Carol Haley, Ph.D.
Deputy Associate Director for Policy and Regulations
Office of the Director
CVM, HFV-6

SUBJECT: Docket 92S-0251

TO: Chief, Dockets Management Branch, HFA-305

Pursuant to 21 CFR Part 11.2(b)(2), and on behalf of the Center for Veterinary Medicine (CVM), we are pleased to add this notification of CVM's readiness to accept electronic submissions for New Animal Drug Applications and supporting components - efficacy, chemistry, target animal safety, etc.

Effective date: June 1, 2001

Submissions of this type to CVM should follow the outline in the general guidance documents for New Drug Applications that describe how to submit information by electronic submission:

Guidance for Industry: Providing Regulatory Submissions in Electronic Format - General Considerations (http://www.fda.gov/cder/guidance/2867fnl.pdf)

Guidance for Industry: Providing Regulatory Submissions in Electronic Format - NDA (http://www.fda.gov/cder/guidance/2353fnl.pdf)

Electronic copies of the guidance documents may be obtained on the Internet from CDER home page at http://www.fda.gov/cder/. Additional guidance describing acceptance criteria for electronic submissions to CVM is contained in CVM's Guidance for Industry #108 entitled "How to Use E-Mail to Submit information to the Center for Veterinary Medicine", which is located at http://www.fda.gov/cvm/.

For information regarding the receiving units (offices, divisions, etc.) that will accept this type of electronic submission and for information regarding types of acceptable electronic media, contact Elizabeth L. Parbuoni, HFV-16, 7519 Standish Place, Rockville, Maryland 20855, 301-827-4621.

Please place this notification on the official docket, 92S-0251.

92S-0251

m 13