and other materials relating to the contemplated license should be directed to Thomas E. O'Toole, Deputy Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Mailstop E–67, Atlanta, GA 30333, telephone: (404) 639–6270; facsimile: (404) 639–6266. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within sixty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

Dated: May 10, 1999.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–12206 Filed 5–13–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0389]

Final Guidance on FDA Approval of New Animal Drugs for Minor Uses and for Minor Species; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled ''Guidance for Industry: FDA Approval of New Animal Drugs for Minor Uses and for Minor Species.'' This guidance document is intended to provide specific guidance on the means for generating effectiveness and safety data to support the approval of new animal drugs for minor uses and minor species.

DATES: Written comments may be provided at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: FDA Approval of New Animal Drugs for Minor Uses and for Minor Species'' to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. Copies of this guidance document may also be obtained from the CVM home page at ''http://www.fda.gov/cvm''. Submit written comments on the guidance document to the Policy and Regulations Team (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Margaret R. Oeller, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7581, e-mail: moeller@bangate.fda.gov.

SUPPLEMENTARY INFORMATION: The major purpose of this guidance document is to suggest means of generating effectiveness and safety data to support the approval of minor use new animal drugs. Minor use of a new animal drug is defined as use in a minor species or use in any animal species for a condition that is rare or that occurs in limited geographic areas. Minor species are defined by exclusion, as any species other than major species. Major species are defined as cattle, swine, chickens, turkeys, horses, dogs, and cats. According to current regulations, sheep are a minor species except with respect to human food safety data collection requirements, for which sheep are considered major species.

The guidance document, as applied to minor use new animal drugs, does not lessen the legal requirements for demonstrating the safety and effectiveness of a new animal drug. Instead, the guidance document suggests possible means of generating safety and effectiveness data to satisfy these requirements.

In the **Federal Register** of September 29, 1997 (62 FR 50952), FDA published a notice of availability of a draft guidance on this subject. The notice gave interested persons an opportunity to submit comments by December 29, 1997. Seven comments were received by industry and trade associations. FDA considered these comments and revised the draft guidance document where appropriate.

This guidance document is intended to reflect the current way that animal drugs are approved for minor species and minor uses. The Animal Drug Availability Act of 1996 required CVM to examine the way that these products are approved and to propose means to facilitate such approvals. In the **Federal Register** of October 29, 1998 (63 FR 58056), CVM published a notice of the availability of its report proposing several options to encourage animal drug approvals for minor species and for minor uses. It is very likely that additional policies and programs will be implemented over the next few years to accomplish this goal. Because policies and programs may change, sponsors are encouraged to contact CVM early in project development to determine the most efficient path to approval of their products. If any program and policy changes affect the policies in this guidance, CVM will revise this final guidance.

The final guidance represents the agency's current thinking on the means of generating efficacy and safety data to support approval of new animal drug applications for minor use new animal drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. CVM will periodically review the comments concerning the document and, when appropriate, amend the guidance.

Dated: May 5, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–12179 Filed 5–13–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1089]

Year 2000 (Y2K) Computer Compliance Guide; Guidance for FDA Personnel

AGENCY: Food and Drug Administration

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new compliance policy guide (CPG) entitled ''Year 2000 (Y2K) Computer Compliance''(section 160–800). This guidance document represents the agency's current thinking on the manufacturing and distribution of domestic and imported products regulated by FDA using computer systems that may not perform properly before, or during, the transition to the year 2000 (Y2K). The text of the CPG is included in this notice. This compliance guidance document is an update to the Compliance Policy Guides Manual (August 1996 edition). It is a new CPG,