acquire FFE Financial Corp., Englewood, Florida, and thereby indirectly acquire First of Englewood, F.S.B., Englewood, Florida, and thereby engage in operating a savings association, pursuant to § 225.25(b)(9) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, February 14, 1996.

Barbara R. Lowrey,

Associate Secretary of the Board.

[FR Doc. 96–3784 Filed 2–20–96; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92D–0287]

Generic Animal Drug Products Containing Fermentation-Derived Drug Substances; Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance on Generic Animal Drug Products Containing Fermentation-Derived Drug Substances.'' The guidance is intended to provide sponsors with information that will enable them to submit complete and well-organized chemistry and manufacturing and control information for applications for generic animal drug products containing fermentation-derived drug substances. FDA invites interested persons to submit written comments on this guidance.

DATES: Written comments on this guidance document may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance on Generic Animal Drug Products Containing Fermentation-Derived Drug Substances'' to the Communications and Education Branch (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2701.

SUPPLEMENTARY INFORMATION: The sponsor of a new animal drug application (NADA) is required to submit to FDA the chemistry and manufacturing and control information necessary to support their submission. This information is generally described in 21 CFR 514.1 for original NADA's and in 21 CFR 514.8 for supplements to approved NADA's. The chemistry and manufacturing and control information requirements are identical for original abbreviated new animal drug applications (ANADA's) and supplements to approved ANADA's.

Additionally, the manufacturing process must meet current good manufacturing practice (CGMP) regulations. The CGMP requirements are described in 21 CFR parts 210 and 211 for pharmaceutical dosage forms and in 21 CFR part 226 for Type A medicated articles.

The Center for Veterinary Medicine believes that the guidance document will provide sponsors with information that will enable them to submit complete and well-organized chemistry and manufacturing and control data and information for ANADA's for animal drug products containing fermentation-derived drug substances.

In contrast to the general description of requirements in the Code of Federal Regulations, the guidance document provides specific manufacturing information recommendations for antibiotic new drug substances, biomass drug substances, and the finished drug product. In addition, it provides guidance for conducting comparison studies between the generic drug product and the pioneer drug product. The guidance document also describes acceptable fermentation organisms, antibiotic new drug substances, and biomass drug substances.

A person may follow the guidance or may choose to follow alternate procedures or practices. If a person chooses to use alternate procedures or practices, that person may wish to discuss the matter further with the agency to prevent an expenditure of money and effort on activities that may later be determined to be unacceptable to FDA. Although this guidance document does not bind the agency or the public, and it does not create or confer any rights, privileges, or benefits for or on any person, it represents FDA's current thinking on generic animal drug products containing fermentation-derived substances. When a guidance document states a requirement imposed by statute or regulation, the requirement is law and its force and effect are not changed in any way by virtue of its inclusion in the guidance.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 13, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–3733 Filed 2–20–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Renewals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces the renewal of certain FDA advisory committees by the Commissioner of Food and Drugs. The Commissioner has determined that it is in the public interest to renew the charters of the committees listed below for an additional 2 years beyond charter expiration date. The new charters will be in effect until the dates of expiration listed below. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463 (5 U.S.C. app. 2)).

DATE: Authority for these committees will expire on the dates indicated below unless the Commissioner formally determines that renewal is in the public interest.