

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.

Name of committee	Date of expiration
National Mammography Quality Assurance Advisory Committee	July 6, 1997
Nonprescription Drugs Advisory Committee	August 27, 1997
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants	December 2, 1997
Food Advisory Committee	December 18, 1997
Vaccines and Related Biological Products Advisory Committee	December 31, 1997
Advisory Committee for Pharmaceutical Science (Formerly Generic Drugs Advisory Committee)	January 22, 1998

FOR FURTHER INFORMATION CONTACT:

Donna M. Combs, Committee Management Office (HFA-306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2765.

Dated: February 9, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96-3734 Filed 2-20-96; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration**Agency Information Collection Activities: Proposed Collection; Comment Request**

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to

minimize the information collection burden.

Type of Information Collection Request: New collection; **Title of Information Collection:** Federally Qualified Health Center (FQHC) Survey; **Form No.:** HCFA-R-188; **Use:** This survey is needed and will be used by HCFA to evaluate the FQHC Medicare benefit. Respondents will be all Medicare certified FQHC's. **Frequency:** On occasion; **Affected Public:** Not-for-profit institutions, and business or other for-profit; **Number of Respondents:** 1,489; **Total Annual Responses:** 1,489; **Total Annual Hours Requested:** 496.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 12, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources.

[FR Doc. 96-3745 Filed 2-20-96; 8:45 am]

BILLING CODE 4120-03-P

Information Collection Requirements Submitted for Public Comment: Submission for Office of Management and Budget (OMB) Review

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this notice announces that the Information Collection Requirement abstracted below has been submitted to the Office of Management and Budget (OMB) for review and comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to

minimize the information collection budget.

1. Type of Information Collection Request: New; **Title of Information Collection:** Medicare Carrier Provider/Supplier Enrollment Application; **Form No.:** HCFA-R-186; **Use:** This information is needed to enroll providers/suppliers by identifying them, verifying their qualifications and eligibility to participate in Medicare, and to price and pay their claims correctly. **Frequency:** Initial Application; **Affected Public:** Business or other for profit, Federal Government; **Number of Respondents:** 160,000; **Total Annual Hours Requested:** 240,000.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collection should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: February 14, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff.

[FR Doc. 96-3862 Filed 2-20-96; 8:45 am]

BILLING CODE 4120-03-P

Privacy Act of 1974; Systems of Records

AGENCY: Department of Health and Human Services (HHS), the Health Care Financing Administration (HCFA).

ACTION: Notice of proposed new routine use for existing and future systems of records.

SUMMARY: HCFA proposes revising the systems notices for all of its existing and future systems of records to include a routine use to allow for the disclosure of information, without the individual's consent, to the Social Security Administration (SSA) in order to enable SSA to assist HCFA in the implementation and maintenance of the Medicare and Medicaid programs.

This new routine use is necessary due to the establishment of SSA as a separate agency which is not a part of HHS. Prior to March 31, 1995, SSA and HCFA were components within HHS and, as such, enjoyed the benefits of the special relationship afforded members of the same Department. One of these benefits was the ability to disclose and