Board of Governors of the Federal Reserve System, February 23, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95-4973 Filed 2-28-95; 8:45 am]

BILLING CODE 6210-01-F

Harrison Bankshares, Inc.; Notice of Application to Engage de novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices.'' Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 15, 1995.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. Harrison Bankshares, Inc., Lost Creek, West Virginia; to engage *de novo* through Harrison Mortgages, Inc., Lost Creek, West Virginia; in originating mortgage loans, pursuant to § 225.25(b)(1) of the Board's Regulation Y.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94D–0401]

Revised Bioequivalence Guideline; Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guideline entitled ''Bioequivalence Guideline (Draft) 1994'' prepared by the Center for Veterinary Medicine (CVM). The draft guideline, which is a revision of the 1990 version, covers general considerations, blood level studies, pharmacologic end-points, clinical end-points, and human food safety. The draft guideline is intended to assist sponsors of new animal drug applications in the submission of data to support approval of these applications.

DATES: Written comments by May 30, 1995.

ADDRESSES: Submit written requests for single copies of the draft guideline entitled ''Bioequivalence Guideline (Draft) 1994'' to the Communications and Education Branch (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1756. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guideline 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. A copy of the draft guideline and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of the draft guideline entitled ''Bioequivalence Guideline (Draft) 1994.'' The draft is based on an April 1990 bioequivalence guideline and a consensus of reports from panel presentations at the 1993 Veterinary Drug Bioequivalence Workshop held in Rockville, MD. Major new topics addressed in the draft guideline include: Bioequivalence overdose studies, testing for multiple strength solid oral dosage forms, assay considerations, area under the curve and maximum blood concentration as pivotal parameters, and blood level studies with good laboratory practice tissue residue depletion for generic products for food animals.

Guidelines are generally issued under §§ 10.85(d) and 10.90(b) (21 CFR 10.85(d) and 10.90(b)), which provide for the use of guidelines to establish procedures or standards of general applicability that are not legal requirements but that are acceptable to FDA. The agency is now in the process of considering whether to revise §§ 10.85(d) and 10.90(b). Therefore, if the agency issues this guideline in final form, it would not be issued under the authority of §§ 10.85(d) and 10.90(b), and would not create or confer any rights, privileges, or benefits for or on any person, nor would it operate to bind FDA in any way. When a guideline states a requirement imposed by statute or regulation, however, the requirement is law and its force and effect are not changed in any way by virtue of its inclusion in the guideline.

Interested persons may, on or before May 30, 1995, submit to the Dockets Management Branch (address above) written comments on the draft guideline. 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 draft guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered to determine whether further amendments to, or revisions of, the draft guideline are warranted.

Dated: February 23, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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