

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 the proposal complies with the standards of section 4 of the BHC Act, including 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" (12 U.S.C. 1843). 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.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 26, 1996.

A. Federal Reserve Bank of Cleveland (R. Chris Moore, Senior Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *Mellon Bank Corporation*, Pittsburgh, Pennsylvania; and The Chase Manhattan Corporation, New York, New York, to acquire through their joint venture ChaseMellon Shareholder Services, L.L.C., Ridgely Park, New Jersey, certain assets relating to the shareholder service business of Wells Fargo Bank, N.A., San Francisco, California, and certain of its affiliated banks pursuant to § 225.25(b)(3) of the Board's Regulation Y. Comments regarding this application must be received by August 23, 1996.

B. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Capitol Bankshares, Inc.*, Madison, Wisconsin; to engage *de novo* through its subsidiary Capitol Mortgage Corporation, Madison, Wisconsin, in making and servicing loans, pursuant to § 225.25(b)(1) of the Board's Regulation Y.

C. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *King Bancshares, Inc.*, Kingman, Kansas to engage *de novo* through its subsidiary, Western Credit, Inc., Hutchinson, Kansas, and thereby engage

in making consumer finance loans pursuant to § 225.25(b)(1)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, August 6, 1996.

Jennifer J. Johnson

Deputy Secretary of the Board

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GENERAL SERVICES ADMINISTRATION

DEPARTMENT OF THE INTERIOR

National Park Service

NATIONAL CAPITAL PLANNING COMMISSION

Memorandum of Agreement Among the General Services Administration, the Department of the Interior— National Park Service and the National Capital Planning Commission

This Memorandum of Agreement (Memorandum) is entered into by and among the General Services Administration (GSA), the Department of the Interior—National Park Service (NPS), and the National Capital Planning Commission (NCPC) for the purpose of ensuring that development and redevelopment within the Pennsylvania Avenue area (as defined in 40 U.S.C. 871(f)) complies with the Pennsylvania Avenue Plan of 1974 (Plan), as amended, and the Pennsylvania Avenue Development Corporation's General Guidelines and Square Guidelines.

Whereas, Public Law 104-134 abolishes the Pennsylvania Avenue Development Corporation (PADC) as of April 1, 1996,

Whereas, Public Law 104-134 requires that all rights, title and interest in and to all property held in the name of the Pennsylvania Avenue Development Corporation be transferred to the General Services Administration or the Department of the Interior—National Park Service,

Whereas, Public Law 104-134 transfers PADC's responsibilities with respect to amending, completing, redeveloping, and ensuring compliance with the Plan to GSA and NCPC,

Whereas, GSA, NPS, and NCPC intend to encourage and facilitate the continued development of the Pennsylvania Avenue area in a manner that builds on and reinforces the past achievements of PADC in restoring Pennsylvania Avenue and its environs,

Whereas, GSA, NPS, and NCPC wish to work in partnership to ensure that the

supervision of the Plan is carried out in a responsible and efficient manner and with appropriate public participation,

The Parties to This Memorandum Do Hereby Agree:

I. Property Development—If GSA decides to develop any property subject to the Plan, the following procedures shall apply:

A. GSA shall prepare (with the advice of NCPC) the Request for Proposals (RFP);

B. GSA shall convene a panel that shall include a representative from NCPC staff to review submitted proposals. The panel, before making its final determination, shall ensure that the selected proposal has been evaluated by a design committee assembled by GSA to ensure high quality building and urban design. The design committee shall include a representative from NCPC. Once GSA has made a selection, GSA shall transmit a copy of the selected proposal to NCPC prior to contract award. NCPC staff will have 10 calendar days to consider whether the proposed selection conforms to the Plan and the General and Square Guidelines. In this document, whenever a review period ends on a Saturday, Sunday or a legal holiday, the review shall conclude on the next day which is not a Saturday, Sunday or legal holiday.

1. If, within the 10 calendar day review period, NCPC staff informs GSA in writing that NCPC believes that the proposed selection conforms with the Plan, the General and Square Guidelines, GSA may proceed to contract award. Unless otherwise agreed, failure of NCPC to act within 10 calendar days shall be construed to mean that NCPC finds that the proposed selection conforms with the Plan, the General and Square Guidelines.

2. If, within the 10 calendar day review period, NCPC staff informs GSA that NCPC believes that the proposed selection does not conform with the Plan, the General and/or Square Guidelines, NCPC shall provide GSA with a written statement explaining NCPC's reasons for so concluding. GSA, upon consideration of NCPC's written statement may either:

a. Accept NCPC's view and either reject the proposal or require the selected offeror to submit a proposed amendment of the Plan, the General and/or Square Guidelines and follow the procedures set forth below in paragraphs I.C. (Plan amendment) and I.D. (General and Square Guidelines amendment), as appropriate, or

b. Work with NCPC staff to reconcile differences in view regarding the need for amendment of the Plan, the General

and/or Square Guidelines. If, after good faith efforts, no resolution is reached, GSA may reject NCPC's view and provide a written memorandum that explains GSA's reasons for rejecting NCPC's view and proceed to contract award.

C. If the proposal that GSA selects requires an amendment to the Plan, GSA shall transmit the selected offeror's proposal for Plan amendment (along with all relevant documentation) to NPS and NCPC for review and comment. GSA's selection of a proposal that will require Plan amendment and referral to NPS and NCPC shall constitute GSA support for Plan amendment.

1. Within 30 calendar days of receiving a proposal for a Plan amendment, NPS shall advise GSA and NCPC whether the proposed Plan amendment affects the Secretary of Interior's responsibilities for the administration, protection, and development of the areas within the Pennsylvania Avenue National Historic Site. If NPS determines that a proposed Plan amendment affects these responsibilities, NPS shall notify GSA and NCPC of its support of, recommended modifications to or opposition to the proposed Plan amendment from the standpoint of the compatibility of the Plan amendment with the Secretary's responsibilities for the administration, protection, and development of the areas within the Pennsylvania Avenue National Historic Site. Unless otherwise agreed, GSA and NCPC may deem a failure of NPS to act within 30 calendar days as a determination that the proposal does not affect the Secretary of the Interior's responsibilities for the administration, protection, and development of the areas within the Pennsylvania Avenue National Historic Site.

2. Within 45 calendar days of receiving a proposal for a Plan amendment and after consideration by NCPC in public session, NCPC shall advise GSA of its views on the proposed Plan amendment. NCPC may support, recommend modification of or oppose the proposed amendment. Unless otherwise agreed, failure of NCPC to act within 45 calendar days shall be deemed acceptance of the proposed Plan amendment.

3. If NPS and NCPC support an amendment to the Plan or if GSA accepts the proposed modifications to the Plan amendment proposal, GSA shall transmit the proposed Plan amendment to the Committee on Transportation and Infrastructure and the Committee on Appropriations of the House of Representatives and the Committee on Environment and Public

Works and the Committee on Appropriations of the Senate. If after 60 legislative days, none of the committees has disapproved of the proposed amendment of the Plan, GSA shall amend the Plan, transmit a copy of the amendment to the Plan to NPS and NCPC, and award the contract.

4. If NPS and/or NCPC does not support amendment of the Plan or if GSA does not accept the proposed modifications to the Plan amendment proposal, GSA, NPS and NCPC will meet and attempt to reconcile their views. If no resolution can be reached, GSA may transmit the proposal for a Plan amendment to the Congressional committees named in paragraph I.C.3. In its submission to the Congressional committees, GSA shall include a written statement from NPS and/or NCPC explaining the reasons for opposing the proposal for Plan amendment and a written statement from GSA and, when appropriate, either NPS or NCPC explaining the reasons for supporting the Plan amendment. If after 60 legislative days, none of the committees has disapproved of the proposed amendment of the Plan, GSA shall amend the Plan, transmit a copy of the amendment to the Plan to NPS and NCPC, and award the contract.

D. If the proposal that GSA selects requires an amendment to the General and/or Square Guidelines, GSA shall transmit the selected offeror's proposal for amendment (along with all relevant documentation) to NCPC for review and comment. GSA's selection of a proposal that will require amendment of the General and/or Square Guidelines and referral to NCPC shall constitute GSA support for the proposed amendment. In considering amendments to the General and/or Square Guidelines, GSA and NCPC shall follow the same procedures and time frames that apply to proposals to amend the Plan (set forth above in I.C.) with the exception that proposed amendments to General and Square Guidelines need not be submitted either to NPS or to the Congressional committees named in paragraph I.C.3.

E. After a contract has been awarded, the selected developer shall work closely with GSA. All designs, drawings, schematics, legal documents or other documents associated with the project shall be submitted to GSA, unless otherwise specified in the contract.

II. Property Redevelopment (Major Modifications)—If a property owner wishes to redevelop property or make any renovations that will change the existing character or use of a building, structure, or site within the Plan area (including substantial remodeling,

conversion, rebuilding, enlargement, extension, or major structural improvement of property, but not including ordinary maintenance or remodeling or changes necessary to continue occupancy):

A. The property owner shall submit its proposed redevelopment plan to GSA and NCPC in writing.

B. GSA shall make an initial determination of whether the proposal conforms to the Plan, the General and Square Guidelines.

1. If GSA believes that the proposal conforms to the Plan, the General and Square Guidelines, GSA shall notify NCPC of its determination. NCPC staff will have 10 calendar days to consider whether the proposal conforms to the Plan, the General and Square Guidelines. Unless otherwise agreed, failure of NCPC to act within 10 calendar days shall be considered agreement with GSA's view.

a. If within the 10 calendar day review period, NCPC staff informs GSA in writing that NCPC believes that the proposal will not require an amendment to the Plan, the General and/or Square Guidelines, GSA may approve the proposal.

b. If within the 10 calendar day review period, NCPC staff informs GSA that NCPC believes that the proposal will require amendment of the Plan, the General and/or Square Guidelines, NCPC shall provide GSA with a written statement explaining NCPC's reasons for concluding that an amendment is necessary. GSA, upon consideration of NCPC's written statement may, at its discretion, either:

(1) Accept NCPC's view and either reject the proposal or require the property owner to submit a proposed amendment to the Plan, the General and/or Square Guidelines (along with all relevant documentation) and follow the procedures set forth in paragraphs I.C. (Plan amendment) and I.D. (General and Square Guidelines amendment), or

(2) Work with NCPC staff to attempt to reconcile differences in view regarding the need for amendment of the Plan, the General and/or Square Guidelines. If, after good faith efforts, no resolution is reached, GSA may reject NCPC's view and approve the proposal. GSA shall provide to NCPC a written memorandum explaining its reasons for rejecting NCPC's view.

2. If GSA believes that the proposal will require amendment of the Plan, the General and/or Square Guidelines and GSA does not support the proposed amendment, the property owner may not proceed with the proposal. If GSA believes that the proposal will require an amendment of the Plan, the General

and/or Square Guidelines and GSA supports such an amendment, GSA shall transmit the proposal (along with all relevant documentation) to NCPC which shall follow the procedures described above in paragraphs I.C. (Plan amendment) and I.D. (General and Square Guidelines amendment), as appropriate. If GSA believes that the proposal will require an amendment of the Plan, GSA will also transmit the proposal (along with all relevant documentation) to NPS and follow the procedures described above in paragraph I.C. (Plan amendment).

III. Priority Redevelopment (Minor Modifications)—If a property owner wishes to make any modifications to a building, structure, or site within the Plan area that will not significantly change the existing character or use of the property (e.g., installation of awnings, outdoor cafe tables), the property owner shall notify GSA and NCPC in writing prior to applying for a D.C. building permit. If, within five calendar days after receiving notification from the property owner, NCPC staff does not notify GSA of its view that the proposed modification does not conform with the Plan, the General and/or Square Guidelines, GSA may proceed with its review of the proposal. If NCPC staff believes that the proposed modification will require an amendment to the Plan, the General and/or Square Guidelines, NCPC and GSA shall follow the procedures set forth in paragraph II.B.1.b. (Property Redevelopment—Major Modification). If GSA determines that the proposed change does not conform to the Plan, the General and/or Square Guidelines, GSA, NPS and NCPC shall follow the procedures set forth above in paragraphs I.C. (Plan amendment) and I.D. (General and Square Guidelines amendment), as appropriate.

IV. GSA Proposals for Plan, General and/or Square Guidelines Amendment—If GSA wishes to amend the Plan, the General and/or Square Guidelines:

A. GSA shall transmit a proposal to amend the Plan (along with all relevant documentation) to NPS and NCPC and follow the procedures set forth in paragraph I.C. Any proposals by GSA to amend the Plan shall be consistent with and respect the goals and objectives stated in Chapter 2 of the original 1974 Plan. These goals include, but are not limited to: Reinforcing Pennsylvania Avenue's role as the physical and symbolic link between the White House and the Capital; making Pennsylvania Avenue function as a bridge between the federal core and the city's downtown areas; encouraging

residential as well as commercial occupancy of Pennsylvania Avenue; encouraging cultural activities along Pennsylvania Avenue; and maintaining a sense of historic continuity and evolution.

B. GSA shall transmit a proposal for an amendment to the General and/or Square Guidelines (along with all relevant documentation) to NCPC and follow the procedures set forth above in paragraph I.D.

V. NCPC Proposals for Plan, General and/or Square Guidelines Amendments—If NCPC wishes to amend the Plan, the General and/or Square Guidelines, NCPC shall transmit a proposal to NPS and GSA (along with all relevant documentation) for consideration. NPS and GSA shall have 45 calendar days to consider proposals for Plan amendment. GSA shall have 30 days to consider proposals for amendment of General and/or Square Guidelines.

A. If NPS and GSA accept NCPC's proposal for Plan amendment, GSA shall transmit the proposal to the Congressional committees named in paragraph I.C.3. If after 60 legislative days, none of the committees has disapproved of the proposed amendment of the Plan, GSA shall amend the Plan and transmit a copy of the amendment to the Plan to NPS and NCPC. If NPS and/or GSA does not accept NCPC's proposal for Plan amendment, NPS, GSA and NCPC shall work together to reconcile differences in view. If, after good faith efforts, no mutually acceptable resolution is reached, GSA may, at its discretion, take no further action with respect to the proposal or transmit the proposal for a Plan amendment to the Congressional committees named in paragraph I.C.3. along with a written statement from NPS and/or GSA explaining the reasons for opposing NCPC's proposed Plan amendment and a written statement from NCPC explaining its reasons for supporting its proposed Plan amendment.

B. If GSA accepts NCPC's proposal for amendment of the General and/or Square Guidelines, GSA shall make the amendments and transmit a copy of the amendment to the General and/or Square Guidelines to NCPC. If GSA does not accept NCPC's proposal for amendment of the General and/or Square Guidelines, GSA shall work with NCPC staff to reconcile differences in view. If after good faith efforts, no resolution is reached, GSA may elect to take no further action with respect to the proposal.

VI. NPS Proposals for Plan Amendment—If NPS wishes to amend

the Plan, it shall transmit a proposal to GSA and NCPC (along with all relevant documentation) for consideration. NCPC and GSA shall have 45 calendar days to consider NPS proposals for Plan amendment.

A. If NCPC and GSA accept NPS's proposal for Plan amendment, GSA shall transmit the proposal to the Congressional committees named in paragraph I.C.3. If after 60 legislative days, none of the committees has disapproved of the proposed amendment of the Plan, GSA shall amend the Plan and transmit a copy of the amendment to the Plan to NPS and NCPC. If NCPC and/or GSA does not accept NPS's proposal for Plan amendment, NPS, GSA and NCPC shall work together to reconcile differences in view. If, after good faith efforts, no mutually acceptable resolution is reached, GSA may, at its discretion, take no further action with respect to the proposal or transmit the proposal for a Plan amendment to the Congressional committees named in paragraph I.C.3. along with a written statement explaining NCPC and/or GSA's reasons for not supporting NPS's proposed Plan amendment and a written statement from NPS explaining its reasons for supporting its proposed Plan amendment.

VII. Review of Building Permits—NCPC staff shall review D.C. building permit applications for non-federal buildings and, where appropriate, certify to the D.C. government, prior to issuance of a building permit, that the work for which the building permit application has been made is not inconsistent with the Plan.

VIII. Savings Provision—Nothing in this agreement should be construed to alter or amend any of NCPC's previously existing responsibilities or authorities, including Section 5 of the National Capital Planning Act, 40 U.S.C. 71d or the Zoning Act, D.C. Code § 5-432, and all applicable NCPC submission requirements.

Dated: July 25, 1996.

General Services Administration.

William R. Lawson,

Assistant Regional Administrator, Public Buildings Service.

Dated: July 25, 1996.

National Capital Planning Commission.

Reginald W. Griffith,

Executive Director, National Capital Planning Commission.

Dated: July 24, 1996.

National Park Service, Department of the Interior.

Robert G. Stanton,

*Field Director, National Capital Area,
National Park Service, Department of Interior.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0226]

Agency Information Collection Activities: Proposed Collection; Comment Request; Reinstatement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements related to the recall of infant formula.

DATES: Submit written comments on the collection of information by October 11, 1996.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1686.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (the PRA), 44 U.S.C. 3501-3520, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor.

“Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, 107.280 (OMB Control Number 0910-0188—Reinstatement)

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant

formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations (part 107, subpart E (21 CFR part 107, subpart E)) implement these statutory provisions.

Section 107.230 requires each recalling firm to evaluate the hazard to human health, devise a written recall strategy, promptly notify each affected direct account (customer) about the recall, and furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 requires the recalling firm to notify the appropriate FDA district office of the recall by telephone within 24 hours, to submit a written report to that office within 14 days, and to submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described above are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market. If manufacturers were not required to provide this information to FDA, FDA's ability to ensure that recalls are conducted properly would be greatly impaired.

FDA estimates the burden of this collection of information as follows: