2. Thrift Savings Plan activity report by the Executive Director.

3. Review of status of new system project by Messrs. Petrick and Stiffler.

4. Review of FY 2000 budget and projected expenditures, approval of FY 2001 proposed budget, and review of FY 2002 estimates.

CONTACT PERSON FOR MORE INFORMATION: Thomas J. Trabucco, Director, Office of External Affairs, (202) 942–1640.

Dated: September 5, 2000.

Elizabeth S. Woodruff,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 00–23194 Filed 9–6–00; 10:36 am]

BILLING CODE 6760–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Community Services; Program Enhance Supplement

AGENCY: Office of Community Services, Administration for Children and Families, Department of Health and Human Services.

ACTION: Publication of notice to the public that the Office of Community Services plans to deviate from the full and open competitive grant process in order to facilitate the award of funds under the Community Services Block Grant Discretionary Program.

SUMMARY: The Administration for Children and Families (ACF), Office of Community Services (OCS), announces that it plans to award a grant under the Community Services Block Grant Discretionary Program to develop, replicate and disseminate an educational tool to be utilized by community development corporations on a national level. This grant will be awarded to National Congress for Community Economic Development.

ADDRESSES:

Name and Address of Grants Officer: Mary Nash, Grants Officer, Administration for Children and Families, Office of Child Support Enforcement—4th Floor, 370 L'Enfant Promenade SW., Washington DC 20447, Telephone: (202) 260–7143

Name and Address of Program Official: Thelma Woodland, Branch Chief, Division of Community Discretionary Programs, Administration for Children and Families, Office of Community Services—5th Floor, 370 L'Enfant Promenade SW, Washington DC 20447, Telephone: (202) 401–5294

Statutory Authority: The community Services Block Grant Act of 1981, as amended, (Section 680 of the community Opportunities, Accountability, and Training and Educational Services (COATS) Act of 1998, authorizes the Secretary to make grants to provide technical and financial assistance for economic development activities designed to address the economic needs of low-income individuals and families, conduct rural community development activities and conduct neighborhood innovation projects.

The Catalog of Federal Domestic Assistance Number is 93.570.

Award Mechanism: Deviation from the competitive process to award a supplement under the Training and Technical Assistance Set-Aside of the Urban and Rural Community Economic Development and Rural Community Facilities Development Program.

Name of Proposed Grantee: National Congress for Community Economic Development.

Estimated Amount of Award and Proposed Period of Support: The proposed amount of the award is $110,000. The proposed period of support will be from 8/1/2000 to 12/31/2001.

Scope and Nature of Project: The funds will be used to expand the scope of work and augment 2000 Year funding to develop, replicate and disseminate an educational tool (a video and accompanying publications) to be utilized by community development corporations on a national level.

Reasons for Less Than Maximum Competition: The National Congress for Community Economic Development (NCCED) has received grants from OCS for the past 5 years. Their most recent grant, funded in 2000, is to help community development corporations (CDCs) access new resources and strengthen their network. NCCED provides training and technical assistance in the areas of resource development, commercial development and building corporate partnerships. NCCED proposes to celebrate the evolution and accomplishments of the field of economic development at its national conference scheduled for mid-October of this year. OCS plans to provide funding for a video with an accompanying booklet and separate historical retrospective publications to be used at this conference. Because of time constraints, it is not feasible to seek open and free competition for this award. In addition, the proposed grantee has exemplified high-quality work in the past and there is no other potential grantee that has the capacity to perform the work desired. NCCED has been a leader in assisting OCS in meeting the needs of CDCs in creating employment and business opportunities for low-income families. The video and other products, once developed, will be an important tool in the delivery of technical assistance to CDCs and in helping to ensure that the economic needs of low income individuals and families of the 21″ century are met through the creation of employment and business opportunities.

Dated: September 5, 2000.

Thornell Page,

Acting Director, Office of Community Services.

[FR Doc. 00–23114 Filed 9–7–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1400]

Draft ''Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications'' dated August 2000. The draft guidance document provides information to sponsors regarding assessment of the reproductive toxicity potential of preventive vaccines for infectious diseases. The draft guidance document, when finalized, is intended to provide sponsors with guidance for the conduct of reproductive toxicity studies for preventive vaccines and to consider establishing clinical pregnancy registries for preventive vaccines indicated for females of childbearing potential and pregnant individuals.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by December 7, 2000.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications'' to the Office of Communication, Training,

and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications'' dated August 2000. Pre-clinical reproductive toxicity studies of vaccines intended for maternal immunization and/or females of child bearing age are critical in assessing the potential for the developmental toxicity of the product. However, the performance and design of pre-clinical reproductive toxicity studies for vaccines to support their use in females of childbearing potential and/or for maternal immunization have not been addressed in the scientific literature. This draft guidance document would provide general and specific considerations that should be taken into account in the assessment of reproductive toxicity for preventive vaccines, and in establishing clinical pregnancy registries for vaccine products post-licensure. The draft guidance document does not address concerns regarding male reproductive toxicity and fertility studies.

This draft guidance document represents the agency's current thinking with regard to the performance and design of pre-clinical reproductive toxicity studies for vaccines. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by December 7, 2000. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at http://www.fda.gov/cber/guidelines.htm.

Dated: August 15, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–23052 Filed 9–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10011]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

We are, however, requesting an emergency review of the Information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because of legislative mandate, Government Performance and Review Act (GPRA) goals, and the potential for public harm. In terms of legislation, the 1997 Balanced Budget Act requires HCFA to offer comparative health plan information for the purposes of ''informed choice.'' In addition, two of the clearly stated goals of the HCFA strategic plan are to ''purchase the best value health care for beneficiaries'' and to ''promote beneficiary and public understanding of HCFA and its programs.''

The improved awareness by beneficiaries of the Medicare program has been incorporated into HCFA's Government Performance and Review Act (GPRA) goals (See: ''Performance Goal M+C1–02: Improve Effectiveness of Dissemination of Medicare Information to Beneficiaries''). Recent analyses of the Medicare Beneficiary Survey data suggest that stage of readiness to make informed choice, which the Pro-Change Behavior Systems Survey will yield, will be a better predictor of knowledge about Medicare than other extant predictors (See: ''Assessing Readiness of Medicare Beneficiaries to Participate in Informed Health Care Choices''). Expediting the clearance of this survey would help HCFA fulfill the goals of HCFA's Government Performance and Review Act (GPRA) as soon as possible.

In addition to the legislative mandate and GPRA, the survey should be expedited to prevent public harm. Recent research conducted by the contractor, Pro-Change Behavior Systems, Inc., has demonstrated that the Medicare beneficiary population contains many who fail to review the adequacy of their health insurance arrangements even on a cursory basis (See: ''Assessing Readiness of Medicare