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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications'' dated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 This draft guidance document would provide general and specific considerations that should be taken into account in the assessment of reproductive toxicity for preventive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 The draft guidance document does not address concerns regarding male reproductive toxicity and fertility studies.

This draft guidance document represents the agency's current thinking with regard to the performance and design of pre-clinical reproductive toxicity studies for vaccines.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]

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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

Beneficiaries to Participate in Informed Health Care Choices''). Unless we are able to identify those individuals and target appropriate outreach and communications strategies to prompt more attention to information about health care choices, at least some beneficiaries will find themselves with inadequate or inappropriate health insurance and may find themselves harmed as a result.

HCFA is requesting OMB review and approval of this collection by September 30, 2000, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by September 26, 2000. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New collection;

Title of Information Collection: Stages of Change Survey for Informed Choice in the Medicare Population;

Form No.: HCFA–10011 (OMB# 0938–NEW);

Use: This is a survey of Medicare beneficiaries in the first step in the application the Transtheoretical Model (the ''stage model'') to informed choice in the Medicare population. The Transtheoretical Model has been applied and proven effective in facilitating behavior change in a wide range of health behaviors including smoking cessation, mammography screening, and safe sex. This work will yield psychometrically sound and externally valid measures of beneficiaries' readiness to make informed choices about health plans, and provide information to HCFA to assist with its national educational campaign to inform beneficiaries about their choices. Stages of Change measures will be administered to 560 Medicare beneficiaries and initial enrollees. This survey research will yield psychometrically sound measures of beneficiaries' readiness to make informed choices about health plans, and provide information to guide HCFA's National Medicare Education Program (NMEP).;

Frequency: Other: One-time survey;

Affected Public: Individuals or households;

Number of Respondents: 560;

Total Annual Responses: 560;

Total Annual Hours: 327.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of Information requirements. However, as noted above, comments on these Information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by September 26, 2000:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards Attention: Dawn Willinghan (HCFA–10011), Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167 Attn: Allison Herron Eydt, HCFA Desk Officer.

Dated: September 28, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–23022 Filed 9–7–00; 8:45 am]

BILLING CODE 4120–03–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–216 & HCFA–2384]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. 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.

(1) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Organ Procurement Organization/Histocompatibility Laboratory Statement of Reimbursable Costs, Manual Instructions and Supporting Regulations Contained in 42 CFR 413.20 and 413.24;

Form No.: HCFA–216 (OMB No. 0938–0102);

Use: This form is required by statute for participation in the Medicare program. The information is used to determine reasonable costs incurred to furnish treatment to End Stage Renal Disease (ESRD) patients by Organ Procurement Organizations and Histocompatibility Laboratories.

Frequency: Annually;

Affected Public: Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government;

Number of Respondents: 108;

Total Annual Responses: 108;

Hours: 4,860.

(2)*Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Third Party Premium Billing Request and Supporting Regulations in 42 CFR 408.6;

Form No.: HCFA–2384 (OMB 0938–0041);

Use: The Third Party Premium Billing Request is used as an authorization form to designate that a family member or other interested party receive the Medicare premium bill and pay it on behalf of a Medicare beneficiary.

Frequency: On occasion;

Affected Public: Individuals or Households;

Number of Respondents: 15,000;

Total Annual Responses: 15,000;

Total Annual Hours: 6,250.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.