

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective July 21, 1999

Dated: June 7, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99-15660 Filed 6-18-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-1265]

Federal/State Memorandum of Understanding on Interstate Distribution of Compounded Drug Products; Draft; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until August 2, 1999, the comment period for the draft standard memorandum of understanding (MOU) entitled "Memorandum of Understanding on Interstate Distribution of Compounded Drug Products" (draft standard MOU) that States may enter into with FDA. FDA published a notice of availability of the draft standard MOU in the **Federal Register** of January 21, 1999 (64 FR 3301). The agency is taking this action in response to numerous requests for an extension of the comment period.

DATES: Written comments on the draft standard MOU may be submitted by August 2, 1999.

ADDRESSES: Copies of the draft standard MOU are available on the Internet at "<http://www.fda.gov/cder/pharmcomp/default.htm>". Submit written requests for single copies of the draft standard MOU entitled "Memorandum of Understanding on Interstate Distribution of Compounded Drug Products" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that

office in processing your request. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Fred Richman, Center for Drug Evaluation and Research (HFD-332), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855-2737, 301-827-7292.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 21, 1999 (64 FR 3301), FDA published a notice announcing the availability of a draft standard MOU entitled "Memorandum of Understanding on Interstate Distribution of Compounded Drug Products" that States may enter into with FDA. The draft standard MOU describes the responsibilities of the States and FDA in investigating and responding to complaints related to compounded drug products distributed interstate and addresses the interstate distribution of inordinate amounts of compounded drug products. FDA has developed this MOU in consultation with the National Association of Boards of Pharmacy under provisions of the Food and Drug Administration Modernization Act of 1997. Interested persons were given until March 22, 1999, to submit written comments on the draft standard MOU.

In the **Federal Register** of March 23, 1999 (64 FR 13997), FDA extended the comment period on the draft standard MOU to June 1, 1999.

In response to numerous requests, FDA has decided to reopen the comment period on the draft standard MOU until August 2, 1999.

Interested persons may, on or before August 2, 1999, submit to the Dockets Management Branch (address above) written comments on the draft standard MOU. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The draft standard MOU and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 11, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99-15582 Filed 6-18-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Assessment of Factors Influencing the Adequacy of Health Care Services to Children in Foster Care and Other Out-of-Home Placements—New

The Maternal and Child Health Bureau of HRSA is planning to conduct a survey of health care services for children in foster care and other out-of-home care settings in the United States. This project is aimed at identifying the contributing factors affecting the delivery of health care services to these children. A survey will be conducted of Child Welfare, Child Health/MCH, Medicaid and Mental Health agencies in all 50 states, the District of Columbia, and five counties in each of 11 states with county-administered child welfare systems. An additional 10 counties will be surveyed to include the counties with the largest population, bringing the total sample to 65 counties. This survey will obtain information describing the range of health service delivery arrangements currently provided, obtain a comprehensive assessment of the organization and delivery of services, and collect data on what different jurisdictions are doing to improve the delivery of health services to this population.

Estimates of the annualized reporting burden are as follows:

| Survey | Number of respondents | Responses per respondent | Total responses | Hours per response | Total hour burden |
|---------------------------|-----------------------|--------------------------|-----------------|--------------------|-------------------|
| Child Welfare | 93 | 1 | 93 | 4 | 372 |
| Child Health | 93 | 1 | 93 | 2.5 | 232 |
| Child Mental Health | 93 | 1 | 93 | 2.5 | 232 |
| Medicaid | 41 | 1 | 41 | 4 | 164 |
| Total | | | 320 | | 1000 |

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: June 15, 1999.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99-15663 Filed 6-18-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Physician Survey on Genetic Testing

Summary: Under the provisions of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 5, 1999, page 519-520 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

Proposed Collection: Title: Physician Survey on Genetic Testing. Type of Information Request: New. Need and Use of Information Collection: The Physicians Survey on Genetic Testing will be used by the National Cancer Institute to establish baseline information on the prevalence of genetic testing for cancer susceptibility among primary care physicians in the United States. The survey will assess whether there are statistically significant differences in (1) self-reported knowledge, current use of, and future intentions to use genetic testing for cancer susceptibility, and (2)

perceptions of barriers to testing, among primary care physicians by their type and location of practice, and recency of training. Primary care physicians (internists, pediatricians, family and general practitioners) will also be compared with specialty groups (gastroenterologists, surgeons, urologists and oncologists) with respect to their use, attitudes toward, and knowledge of, genetic testing for cancer susceptibility. A questionnaire will be administered by mail, telephone, facsimile and Internet, using a nationally representative sample of physicians. The study physicians will select their preferred response mode. Frequency of Response: One-time study. Affected Public: Medical Community. Type of Respondents: Primary care and speciality physicians with active licenses to practice medicine in the U.S. The annual reporting burden is as follows: Estimated Number of Respondents: 1,350; Estimated Number of Responses per Respondent: 1; Average Burden Hours per Response: .250 and Estimated Total Annual Burden Hours Requested; 338. The annualized cost to respondents is estimated at: \$25,313. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms on information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding

the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Louise Wideroff or Andrew Freedman, Epidemiologists, National Cancer Institute, EPN 313, Executive Boulevard MSC 7334, Bethesda, Maryland 20892-7344, Telephone (301) 435-6823 or (301) 435-6819, FAX (301) 435-3710, or E-mail your request, including your address to wideroff@nih.gov or Andrew_Freedman@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: June 11, 1999.

Reesa L. Nichols,

NCI Project Clearance Liaison.

[FR Doc. 99-15636 Filed 6-18-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Research and Development of Software for Managing Distributed Knowledgebases Consisting of Large Numbers of Object of Diverse Categories Spanning Administrative, Scientific and Other Knowledge Domains

The National Cancer Institute (NCI) has extended the deadline for submission of written notices and proposals regarding the CRADA opportunity described in the **Federal Register** Notice number 74, volume 64, page 19183, dated April 19, 1999.