

Application No.	Drug	Applicant
ANDA 88-015	THEO-DUR (Theophylline Sustained-release Capsules) Sprinkle, 75 mg	Do.
ANDA 88-016	THEO-DUR (Theophylline Sustained-release Capsules) Sprinkle, 125 mg	Do.
ANDA 88-022	THEO-DUR (Theophylline Sustained-release Capsules) Sprinkle, 50 mg	Do.
ANDA 88-066	Hydrocortone Bitartrate and Homatropine Methylbromide Syrup, 5 mg/1.5 mg per 5 mL	Halsey Drug Co., 1827 Pacific St., Brooklyn, NY 11233.
ANDA 88-112	Tripodrine (Triprolidine and Pseudoephedrine Hydrochlorides Tablets USP) 2.5 mg/60 mg	Danbury Pharmacal, Inc., 131 West St., Danbury, CT 06810.
ANDA 88-140	Chlorthalidone Tablets USP, 50 mg	Purepac Pharmaceutical.
ANDA 88-178	Hydralazine Hydrochloride Tablets, 50 mg	Do.
ANDA 88-360	Fluocinolone Acetonide Cream USP, 0.025%	Alpharma.
ANDA 88-361	Fluocinolone Acetonide Cream USP, 0.01%	Do.
ANDA 88-950	Tolbutamide Tablets, 500 mg	Purepac Pharmaceutical.
ANDA 88-997	Dexamethasone Elixir USP, 0.5 mg/5 mL	Alpharma.
ANDA 89-754	Hydrocortisone Cream USP, 2.5%	Do.
ANDA 89-840	Procainamide Hydrochloride Extended-release Tablets, 500 mg	Inwood Laboratories.

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of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 25, 1997.

Dated: September 11, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97-25369 Filed 9-24-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Delegation of Authority

Notice is hereby given that I have delegated to the Director, Centers for Disease Control and Prevention, with authority to redelegate, the following authorities vested in the Secretary of Health and Human Services under Title XXVI of the Public Health Service Act, "Health Care Services Program," and the Ryan White Care Act Amendments of 1996 (P.L. 104-146), as amended hereafter, insofar as these authorities pertain to the functions assigned to the Centers for Disease Control and Prevention:

Section 2625—CDC Guidelines for Pregnant Women

Section 2626—Perinatal Transmission of HIV Disease; Contingent Requirement Regarding State Grants Under This Part

Section 2628—Report by the Institute of Medicine

Sections 2641-2650—Formula Grants for States

Sections 2661-2667—General Provisions

Section 2675—Coordination

Section 2680—Grants to States and political subdivisions of States to implement guidelines and model curriculum for health workers and public safety workers, including emergency response employees.

Sections 2681-2690—Notification of Possible Exposure to Infectious Diseases

The Centers for Disease Control and Prevention and the Health Resources and Services Administration shall cooperate in the implementation of Section 2626(e).

This delegation shall be excised under the Department's existing delegation of authority and policy on regulations.

This delegation became effective upon date of signature. In addition, I have affirmed and ratified any actions taken by the Director, Centers for Disease Control and Prevention or his subordinates which involved the exercise of the authorities delegated herein prior to the effective date of the delegation.

Dated: September 15, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97-25467 Filed 9-24-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-97]

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

AGENCY: Health Care Financing Administration.

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.

Type of Information Collection Request: Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Requirement to Disclose HMO Financial Information to Members and Supporting Regulations in 42 CFR 417.124; *Form No.:* HCFA-R-0097 (OMB 0938-0472); *Use:* Federally

qualified HMOs must meet the full and fair disclosure requirements at 42 CFR 417.124. It requires a written description of an HMO's benefits, coverage, procedures for obtaining benefits, circumstances under which benefits may be denied, premium rates, grievance procedures, service area, provider location(s), hours of service, participating providers, and the financial condition of the HMO.

Frequency: On occasion; *Affected Public:* Business or other for profit, and Not for profit institutions; *Number of Respondents:* 386; *Total Annual Responses:* 386; *Total Annual Hours:* 1.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 19, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 97-25470 Filed 9-24-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental Research; Notice of Closed Meeting of the National Institute of Dental Research Special Grants Review Committee

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Name of Committee: National Institute of Dental Research Special Grants Review Committee.

Date: October 16-17, 1997.

Time: 8:30 a.m. to Adjournment.

Place: Gaithersburg Hilton Hotel, 620 Perry Parkway, Gaithersburg, Maryland 20814.

Contact Person: Dr. William Gartland, Scientific Review Administrator, NIDR Special Grants Review Committee, Natcher Building, Room 4AN-38E, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To review and evaluate grant applications and/or contract proposals.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.121, Dental Research Institute; National Institutes of Health, HHS)

Dated: September 19, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-25425 Filed 9-24-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental Research; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Dental Research Special Emphasis Panel (SEP) meetings:

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Review of R13 grant (98-02).

Date: October 1, 1997.

Time: 1:00 p.m.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact Person: Dr. George Hausch, Chief, Grants Review Section, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Review of R01 grant (98-03).

Date: October 13, 1997.

Time: 10:00 a.m.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact Person: Dr. George Hausch, Chief, Grants Review Section, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Review of R01 grant (98-04).

Date: October 20, 1997.

Time: 1:00 p.m.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact Person: Dr. George Hausch, Chief, Grants Review Section, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Review of R01 grant (98-06).

Date: October 22, 1997.

Time: 10:00 a.m.

Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact Person: Dr. Philip Washko, Scientist Review Administrator, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

These meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research)

Dated: September 19, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-25426 Filed 9-24-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health (NIH)

National Institute on Aging; Notice of Meeting of the Board of Scientific Counselors, National Institute on Aging

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Institute on Aging, October 21-23, 1997 to be held at the Gerontology Research Center, Baltimore, Maryland. On Wednesday, October 22, the meeting will be open to the public for the review