(b) Culture-derived impurities include inducers (polynucleotides, viruses) antibiotics, serum, other media components.

(c) Downstream-derived impurities include enzymes, chemical/biochemical processing reagents (e.g., cyanogen bromide, guanidine, oxidizing and reducing agents), inorganic salts (e.g., heavy metals, arsenic, non metallic ion), solvents, carrier/ligands (e.g., monoclonal antibodies), other leachables.

6.2.2 Product-related impurities

The following represents the most frequently encountered molecular variants of the desired product and lists relevant technology for their assessment:

(a) Truncated forms. Cellular peptidases may catalyze the removal of amino acids or catalyze internal cleavages. This may be detected by HPLC or SDS–PAGE. Peptide mapping may be useful, depending on the property of the variant.

(b) Deamidated, isomerized, mismatched S–S linked, oxidized forms may need considerable effort in isolation and characterization in order to identify the type of chemical modification(s) and amino acid residue(s) involved. Chromatographic and/or electrophoretic methods (e.g., HPLC, capillary electrophoresis, mass spectroscopy, circular dichroism) may be utilized to isolate and characterize such variants.

(c) The category of aggregates includes dimers and higher multiples of the molecular entity. These are generally resolved from the active moiety and quantitated by size exclusion chromatography (e.g., SE–HPLC). Degradants identified from stability studies as being generated in significant amounts should be tested for and monitored against appropriately established acceptance criteria.

Dated: June 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15193 Filed 6–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0285]

Sanofi Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 21 New Drug Applications and 62 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of May 12, 1998 (62 FR 26191). The document announced the withdrawal of approval of 21 new drug applications (NDA's) and 62 abbreviated new drug applications (ANDA's). The document was published with an error in the identification of NDA for Pipanol Powder and Tablets (trihyphenidyl) held by Sanofi Pharmaceuticals, Inc. This document corrects that error.

EFFECTIVE DATE: June 11, 1998.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

In FR Doc. 98–12613, appearing on page 26191 in the **Federal Register** of Tuesday, May 12, 1998, the following correction is made:

On page 26191, in the table, in the first column, the first entry ''NDA 4–496'' is corrected to read ''NDA 7–796''.

Dated: June 3, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15338 Filed 6–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0532]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Radioactive Drug Research Committee (RDRC) Report on Research Use of Radioactive Drug Membership Summary and Radioactive Drug Research Use of Radioactive Drug Study Summary'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 9, 1998 (63 FR 1484), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0053. The approval expires on May 31, 2001.

Dated: June 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15191 Filed 6–8–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1044–N]

Medicare Program; June 22, 1998, Meeting of the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for June 22, 1998, from 8:30 a.m. until 5 p.m., E.S.T.

ADDRESSES: The meeting will be held in Room 800, 8th Floor, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Aron Primack, MD, MA, FACP, Executive Director, Practicing Physicians Advisory Council, Room 435–H, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, DC 20201, (202) 690–7874

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health

Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term.

The Council held its first meeting on May 11, 1992.

The current members are: Jerold M. Aronson, M.D.; Richard Bronfman, D.P.M.; Wayne R. Carlsen, D.O.; Gary C. Dennis, M.D.; Mary T. Herald, M.D.; Ardis Hoven, M.D.; Sandral Hullett, M.D.; Jerilynn S. Kaibel, D.C.; Marie G. Kuffner, M.D.; Marc Lowe, M.D.; Derrick K. Latos, M.D.; Sandra B. Reed, M.D,; Susan Schooley, M.D.; Maisie Tam, M.D.; and Kenneth M. Viste, Jr., M.D. The chairperson is Kenneth M. Viste, Jr., M.D. The vice chairperson is Marie G. Kuffner, M.D.

Council members will receive updates on Documentation Guidelines, HIPPA Administration Simplification Rule, Medicare+Choice, Practice Expense Proposed Rule, and Year 2000 Information System Issues. The agenda will provide for discussion and comment on the following topics:

- Quality Improvement and Evidenced Based Decision Making, and
- Chief Financial Officer Audit.

Individuals or organizations that wish to make 5-minute oral presentations on the agenda issues should contact the Executive Director by 12 noon, June 10, 1998, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to the Executive Director no later than 12 noon, June 17, 1998. Anyone who is not scheduled to speak may submit written comments to the Executive Director by 12:00 noon, June 17, 1998. The meeting is open to the public, but attendance is limited to the space available.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a))

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 4, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 98–15381 Filed 6–5–98; 10:46 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

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 meetings:

Name of Committee: National Institute on Aging Initial Review Group, Sociology Aging Review Committee.

Dates of Meeting: June 11–12, 1998.

Times of Meeting: June 11—6:00 p.m. to recess; June 12—8:30 a.m. to adjournment.

Place of Meeting: ANA Hotel, Washington, D.C.

Purpose/Agenda: To review grant applications.

Contact Person: Dr. Mary Ann Guadagno, Scientific Review Administrator, Gateway Building, Room 2C212, National Institutes of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

Name of SEP: National Institute on Aging Special Emphasis Panel, Epidemiology of Dementia in an Urban Community.

Date of Meeting: June 12, 1998.

Time of Meeting: 8:30 a.m. to adjournment.

Place of Meeting: Radisson Empire Hotel, New York, NY 10023.

Purpose/Agenda: To review project application.

Contact Person: Dr. William Kachadorian, Scientific Review Administrator, Gateway Building, Room 2C212, National Institutes of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

This notice is being published less than 15 days prior to the above meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Name of SEP: National Institute on Aging Special Emphasis Panel, Biology and Neuroscience of Aging and Geriatrics, Minority Dissertation Review—Panel B (teleconference).

Date of Meeting: June 17, 1998.

Time of Meeting: 1:00 p.m. to adjournment.

Place of Meeting: Gateway Building, Room 2C212, 7201 Wisconsin Avenue, Bethesda, Maryland 20892.

Purpose/Agenda: To review small grant applications.

Contact Person: Dr. Paul Lenz, Scientific Review Administrator, Gateway Building, Room 2C212, National Institutes of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

Name of SEP: National Institute on Aging Special Emphasis Panel, Psychology and Sociology of Aging Minority Dissertation Review (Teleconference).

Date of Meeting: June 24, 1998.

Time of Meeting: 1:00 p.m. to adjournment.

Place of Meeting: Gateway Building, Room 2C212, 7201 Wisconsin Avenue, Bethesda, Maryland 20892.

Purpose/Agenda: To review small grant applications.

Contact Person: Dr. Paul Lenz, Scientific Review Administrator, Gateway Building, Room 2C212, National Institutes of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

Name of SEP: National Institute on Aging Special Emphasis Panel DNA Repair, Mutations and Cellular Aging and Mechanism of Myocardial Aging.

Dates of Meeting: July 7–9, 1998.

Times of Meeting: July 7–8:00 p.m. to recess; July 8–8:30 a.m. to recess; July 9–8:30 a.m. to adjournment.

Place of Meeting: Copley Marriott, Boston, Massachusetts.

Purpose/Agenda: To review grant applications.

Contact Person: Dr. James Harwood, Scientific Review Administrator, Gateway Building, Room 2C212, National Institutes of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

These meetings will be closed in accordance with the provisions set forth in secs. 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 constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health)

Dated: June 2, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–15286 Filed 6–8–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose