(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