believe that there are significant, complex scientific and regulatory issues relating to human and animal safety that would need to be resolved by Congress before a similar scheme for animal supplements could be put into place. Accordingly, FDA has concluded that animal dietary supplements are not covered by the DSHEA.

Interested persons may, on or before July 22, 1996, submit to the Dockets Management Branch (address above) written comments on this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 11, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–9780 Filed 4–19–96; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

[Docket No. 84N–0102]

Cumulative List of Orphan Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a cumulative list of designated orphan drugs and biologics as of December 31, 1995. FDA has announced the availability of previous lists, which are brought up-to-date monthly, identifying the drugs and biologicals granted orphan-drug designation pursuant to the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the list of current orphan-drug designations and of any future lists are or will be available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Peter Vaccari, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0983.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan-drug designation under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act, which requires public notification of designations, FDA maintains a list of designated orphan drugs and biologicals. This list is made current on a monthly basis and is available upon request from OPD (contact identified above). At the end of each calendar year, the agency publishes an up-to-date cumulative list of designated orphan drugs and biologicals, including the names of designated compounds, the specific disease or condition for which the compounds are designated, and the sponsors' names and addresses. The cumulative list of compounds receiving orphan-drug designation through 1988 was published in the Federal Register of April 21, 1989 (54 FR 16294). This list is available on request from FDA's Dockets Management Branch (address above). Those requesting a copy should specify the docket number found in brackets in the heading of this document.

The list that is the subject of this notice consists of designated orphan drugs and biologicals through December 31, 1995, and, therefore, brings the March 2, 1993 (58 FR 12041), publication up-to-date.

The orphan-drug designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing an orphan drug or biological must apply for orphan-drug designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested. (See 53 FR 47577, November 23, 1988.) Copies of the regulations (see 57 FR 62076, December 29, 1992) for use in preparing an application for orphan-drug designation may be obtained from OPD (address above).

The names used in the cumulative list for the drug and biological products that have not been approved or licensed for marketing may not be the established or proper names approved by FDA for these products if they are eventually approved or licensed for marketing. Because these products are investigational, some may not have been reviewed for purposes of assigning the most appropriate established proper name.

Dated: April 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–9782 Filed 4–19–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Tentative Schedule of Meetings for 1996

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for the remainder of 1996. At the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. The IOM recommended that the agency publish an annual tentative schedule of its meetings in the Federal Register. In response to that recommendation, FDA is publishing its annual tentative schedule of meetings for the remainder of 1996.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: The IOM, at the request of the Commissioner, undertook a study of the use of FDA's advisory committees. In its final report, the IOM recommended that FDA adopt a policy of publishing an advance yearly schedule of its upcoming public advisory committee meetings in the Federal Register. FDA has implemented this recommendation. A tentative schedule of forthcoming meetings will be published annually in the Federal Register. The annual publication of tentatively scheduled advisory committee meetings will provide both advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA's upcoming advisory committee meetings. The schedule is tentative and amendments to this notice will not be published in the Federal Register. FDA will, however, publish a Federal Register notice 15 days in advance of each upcoming advisory committee meeting, announcing the meeting (21 CFR 14.20).

The following list announces FDA's tentatively scheduled advisory committee meetings for the remainder of 1996:

Committee name	Dates of meetings
OFFICE OF THE COMMISSIONER	
Board of Tea Experts	No meetings planned
Science Board to the Food and Drug Administration	July 2 (subcommittee meeting) August 16 (subcommittee meeting) October 11 (subcommittee meeting) November 12 December 2 (subcommittee meeting)
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH	
Allergenic Products Advisory Committee	November 15
Biological Response Modifiers Advisory Committee	June 10–11 October 21–22
Blood Products Advisory Committee	June 20–21 September 26–27 December 12–13
Vaccines and Related Biological Products Advisory Committee	April 10–11 July 10–11 October 29–30
CENTER FOR DRUG EVALUATION AND RESEARCH	
Advisory Committee for Pharmaceutical Science (formerly Generic Drugs Advisory Committee.	August 15–16
Advisory Committee for Reproductive Health Drugs (formerly Fertility and Maternal Health Drugs Advisory Committee).	June 27–28 October 24–25
Anesthetic and Life Support Drugs Advisory Committee	April 29–30
Anti-Infective Drugs Advisory Committee	July 25–26 October 17–18
Antiviral Drugs Advisory Committee	June 6–7 August 1–2 October 3–4 December 12–13
Arthritis Advisory Committee	May 7 July 9–10 September 10–11 November 19–20
Cardiovascular and Renal Drugs Advisory Committee	May 2–3 October 24–25
Dermatologic and Ophthalmic Drugs Advisory Committee	November 21–22
Drug Abuse Advisory Committee	August 15–16
Endocrinologic and Metabolic Drugs Advisory Committee	June 27–28 September 26–27 December 10–11
Gastrointestinal Drugs Advisory Committee	September 19–20
Medical Imaging Drugs Advisory Committee	November 22
Nonprescription Drugs Advisory Committee	April 19 June 13–14 August 1–2 October 9–11 December 16–17
Oncologic Drugs Advisory Committee	April 19 June 13–14 September 11–12 December 16–17
Peripheral and Central Nervous System Drugs Advisory Committee	June 3–4 September 16–17 December 2–3
Psychopharmacologic Drugs Advisory Committee	July 15–16 October 21–22
Pulmonary-Allergy Drugs Advisory Committee	December 16–17
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	
Food Advisory Committee	July 22–24 September 23–25 November 18–20
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	
Device Good Manufacturing Practice Advisory Committee	No meetings planned
Medical Devices Advisory Committee	
Anesthesiology and Respiratory Therapy Devices Panel	June 21 September 20 November 22
Circulatory System Devices Panel	June 17–18

Committee name	Dates of meetings
	November 4–5
Clinical Chemistry and Clinical Toxicology Devices Panel	No meetings planned
Dental Products Panel	June 6–7 (Plaque subcommittee meeting)
	August 5–6 (Plaque subcommittee meeting)
	September 10–12
	December 10–11 (Plaque subcommittee meeting)
	December 10–12
Ear, Nose, and Throat Devices Panel	June 10–11
	September 4–5
	December 12–13
Gastroenterology-Urology Devices Panel	September 5–6
	December 12–13
General and Plastic Surgery Devices Panel	No meetings planned
General Hospital and Personal Use Devices Panel	June 17–18
	September 16–17
Hematology and Pathology Devices Panel	August 8–9
	October 24–25
Immunology Devices Panel	June 7
	August 8
	December 6
Microbiology Devices Panel	No meetings planned
Neurological Devices Panel	September 11
Obstetrics-Gynecology Devices Panel	July 22–23
	October 21–22
Ophthalmic Devices Panel	April 1
	July 25–26
	October 17–18
Orthopedic and Rehabilitation Devices Panel	May 22–23
Radiological Devices Panel	May 13
	September 16
	November 18
National Mammography Quality Assurance Advisory Committee	April 23–25
	July 9–10
	September 25–27
	December 10–12
Technical Electronic Product Radiation Safety Standards Committee	April 9–10
CENTER FOR VETERINARY MEDICINE	
Veterinary Medicine Advisory Committee	May 29

Committee name	Dates of meetings
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants.	September 16–17
Science Board to the National Center for Toxicological Research	November 13–14

Dated: April 12, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–9781 Filed 4–19–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–R–79, HCFA–R–43, HCFA–222]

Agency Information Collection Activities: Proposed Collection; 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 summaries of proposed collection for public comment. 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:* Payment Adjustment for Sole Community Hospitals; *Form No.:* HCFA-R–79; *Use:* Hospitals designated as ''Sole Community Hospitals'' that experience a five percent decrease in discharges in one cost reporting period, as compared to the previous period, due to unusual circumstances, beyond its control, may request an adjustment to its Medicare payment amount. *Frequency:* On