Blankenbaker, Scientific Review Administrator, Scientific Review Branch, Agency for Health Care Policy and Research, Suite 602, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594–1438.

Agenda items for all meetings are subject to change as priorities dictate.

Dated: January 30, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95–2690 Filed 1–31–95; 10:57 am]

BILLING CODE 4160–90–P

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Food Advisory Committee

Date, time, and place. February 22, 1995, 9:30 a.m., Food and Drug Administration, Center for Food Safety and Applied Nutrition, Federal Bldg. 8, rm. 6823, 200 C St. SW., Washington, DC.

Type of meeting and contact person. A meeting of a task group on *Vibrio vulnificus* of the Food Advisory Committee with invited guests from the National Advisory Committee on Microbiological Criteria for Foods will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting. Open task group discussion, 9:30 a.m. to 12 m.; open public hearing, 12 m. to 1 p.m., unless public participation does not last that long; Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS–5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4727, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Food Advisory Committee, code 10564.

General function of the committee. The committee provides advice on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade.

Open committee discussion. The task group will discuss the objective, the target audience, the implementation strategy and measurement of effectiveness for a *Vibrio vulnificus* consumer education initiative being planned by FDA. The initiative is expected to be funded by money from the National Marine Fisheries Service via an interagency agreement with FDA.

Agenda—Open public hearing. Interested persons may present data, information or views, orally or in writing, on issues pending before the task group. Those desiring to make formal presentations should notify the contact person before February 17, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments. Written statements may be submitted to the task group or committee at any time through the contact person.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory

Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: January 27, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–2504 Filed 2–1–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPD–812–NC]

RIN 0938–AG83

Medicare Program; Criteria for Medicare Coverage of Lung Transplants

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

ACTION: Notice with comment period.

SUMMARY: This notice announces a Medicare national coverage decision for lung and heart-lung transplantations. Lung transplantation refers to the transplantation of one or both lungs from a single cadaver donor. Heart-lung transplantation refers to the transplantation of one or both lungs and the heart from a single cadaver donor.

We have determined that, under certain circumstances, lung transplants and heart-lung transplants are a medically reasonable and necessary service when furnished to patients with progressive end-stage pulmonary or cardiopulmonary disease and when furnished by Medicare participating facilities that meet specific criteria, including patient selection criteria.

DATES: This notice is effective February 2, 1995. For information on how this notice effects Medicare payment for lung and heart-lung transplants, see sections E and F of this notice.

ADDRESSES: *Applications.* A facility seeking Medicare coverage and payment for lung transplantation should mail 10 copies of the application to the address below in a manner which provides the facility with documentation that it was received by us: Director, Office of Hospital Policy, Room 189 East High Rise, 6325 Security Boulevard, Baltimore, Maryland 21207.

Comments. Comments will be considered if we received them at the appropriate address, as provided below, no later than 5 p.m. on April 3, 1995.

Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–812–NC, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room 132, East High Rise Building, 6325 Security Building, Baltimore, MD 21207.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–812–NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

If you wish to submit comments on the information collection requirements contained in this rule, you may submit comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Claude Mone, (410) 966–5666.

SUPPLEMENTARY INFORMATION:

I. Background

Administration of the Medicare program is governed by the Medicare law, title XVIII of the Social Security Act (the Act). The Medicare law provides coverage for broad categories of benefits, including inpatient and outpatient hospital care, skilled nursing facility (SNF) care, home health care, and physicians' services. It places general and categorical limitations on the coverage of the services furnished by certain health care practitioners, such as dentist, chiropractors and podiatrists, and it specifically excludes some categories of services from coverage, such as cosmetic surgery, personal comfort items, custodial care, routine physical checkups, and procedures that are not reasonable and necessary for diagnosis or treatment of an illness or injury.

The Act also provides direction as to the manner in which payment is made for Medicare services, the rules governing eligibility for services, and the health, safety, and quality standards to be met in institutions furnishing services to Medicare beneficiaries. The Medicare law does not, however, provide an all-inclusive list of specific items, services, treatments, procedures, or technologies covered by Medicare. Thus, except for the examples of durable medical equipment in section 1861(n) of the Act, and some of the medical and other health services listed in section 1861(s) and 1862(a) of the Act, the Act does not specify medical devices, surgical procedures, or diagnostic or therapeutic services that should be covered or excluded from coverage.

The intention of the Congress, at the time the Medicare Act was enacted in 1965, was that Medicare would provide health insurance to protect the elderly or disabled from the substantial costs of acute health care services, principally hospital care. The program was designed generally to cover services ordinarily furnished by hospitals, SNFs, and physicians licensed to practice medicine. The Congress understood that questions as to coverage of specific services would invariably arise and would require specific coverage decisions by those administering the program. It vested in the Secretary the authority to make those decisions.

Section 1862(a)(1)(A) of the Act prohibits payment for any expenses incurred for items or services ''which are not reasonable or necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'' We have interpreted this statutory provision to exclude from Medicare coverage those medical and health care services that have not been demonstrated by acceptable clinical evidence to be safe and effective. Effectiveness in this context is defined as the probability of benefit to individuals from a medical item, service, or procedure for a given medical problem under average conditions of use, that is, day-to-day medical practice.

To date, the Medicare program has not issued a national coverage policy on lung or heart-lung transplantation. In the absence of national coverage policy, the contractors that process Medicare claims are authorized to develop Medicare coverage policy for their service area using medical literature, the advice of medical consultants and local medical societies, and their private line business practices.

Several contractors have determined lung transplantation to be a Medicare covered service prior to this notice, and a small number of contractors have covered heart-lung transplant. However, most of these contractors do not have a clearly defined coverage policy that would allow a beneficiary to know in advance if the procedure would be covered. Rather, they review each case individually after it has occurred and determine coverage without published