| Application No. | Drug |
|---|---|
| ANDA 88–932 | Reserpine and Hydroflumethiazide Tablets, 0.125 mg/50 mg |

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of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective January 5, 1998.

Dated: November 17, 1997.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 97–31879 Filed 12–4–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Oncologic Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Oncologic Drugs Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA regulatory issues.

*Date and Time*: The meeting will be held on December 18, 1997, 8:30 a.m. to 5:05 p.m., and December 19, 1997, 8 a.m. to 4:35 p.m.

*Location*: Holiday Inn, Versailles Ballrooms I, II, and III, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Person*: Jannette O'Neill-Gonzalez, or Robinette Taylor, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On December 18, 1997, the committee will discuss: (1) New drug application (NDA) supplement 16–295/S–029, Droxia® (hydroxyurea capsules, USP), for the treatment of sickle cell anemia in adult patients to prevent painful crises and to reduce the need for blood transfusions; and (2) NDA 20–798, Depocyt® (cytarabine lipid-particle injection), for the intrathecal treatment of neoplastic meningitis of patients with solid tumors, lymphoma, or leukemia. On December 19, 1997, the committee will discuss: (1) Biologics licensing application (BLA) supplement 97–0501, Proleukin/Aldesleukin (recombinant human interlukin-2), for the treatment of adult patients with metastatic melanoma; and (2) NDA 20–806, Neomark® (broxuridine for injection), for use as a cell proliferation marker to determine the labeling index in breast cancer.

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 10, 1997. Oral presentations from the public will be scheduled between approximately 8:35 a.m. and 9:05 a.m. on December 18, 1997, and between approximately 8:05 a.m. and 8:35 a.m. on December 19, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 10, 1997, 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 requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the December 18, 1997, Oncologic Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Oncologic Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 26, 1997.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 97–31808 Filed 12–4–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0442]**

### Memoranda of Understanding Between the Food and Drug Administration and the United States Department of Agriculture

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) have revised three memoranda of understanding (MOU's) with regard to control of aflatoxin in peanuts, in-shell Brazil nuts, and in-shell pistachio nuts. The purpose of the MOU's is to set forth the responsibility for aflatoxin testing of domestic and imported raw peanuts, imported in-shell Brazil nuts, and imported in-shell pistachio nuts.

**DATES:** The MOU's became effective October 1, 1997.

**FOR FURTHER INFORMATION CONTACT:** Henry Kim, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–0631.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's signed by FDA and other departments, agencies, and organizations shall be published in the **Federal Register**, the agency is publishing three revised MOU's between FDA and USDA that set forth the responsibility for aflatoxin testing of domestic and imported raw peanuts, imported in-shell Brazil nuts, and imported in-shell pistachio nuts.

Dated: November 24, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

The text of the three MOU's follows: Agreement No.

225–96–2001
Revision 1
12–25–MU–335
Revision 1

**Memorandum of Understanding Between the Science and Technology Division of the Agricultural Marketing Service, United States Department of Agriculture and the Food and Drug Administration, Department of Health and Human Services**

PROJECT ..... Aflatoxin testing of domestic and imported peanuts

LEADERS ..... Administrator, Agricultural Marketing Service (AMS), United States Department of Agriculture (USDA) and Associate Commissioner for Regulatory Affairs, Food and Drug Administration (FDA), Department of Health and Human Services (HHS)

LOCATIONS ..... Albany, Ashburn, Blakely, Camilla, and Dawson, Georgia, Dothan, Alabama, Aulander, North Carolina, Madill, Oklahoma, and Suffolk, Virginia

HEADQUARTERS ..... Washington, DC
EFFECTIVE DATE ..... October 1, 1997

LEGAL AUTHORITY ..... The Agricultural Marketing Act of 1946, and the Federal Food, Drug, and Cosmetic Act of 1938, as Amended

REVISION ..... This is a revision of and shall supersede Memorandum of Understanding, FDA-225–96–2001, effective October 1, 1995, between FDA and AMS.

ORGANIZATION ..... The organization shall consist of the leaders, qualified analytical chemists and physical science technicians provided and supervised by the AMS Aflatoxin Supervisor, and technical contacts provided and supervised by the Chief, Technical Services Branch, Science and Technology Division (S&TD), AMS.

BACKGROUND ..... Aflatoxins are toxic metabolites produced by the molds *Aspergillus flavus* and *Aspergillus parasiticus*. If present in sufficient amounts, they may cause acute toxicity and are known to be carcinogens for some animals. Peanuts, tree nuts, corn, and other small grains are susceptible to aflatoxin contamination. The Peanut Administrative Committee (PAC) administers Marketing Agreement 146 with USDA oversight to control the aflatoxin problem in peanuts and ensure the wholesomeness of peanuts moving into channels for human consumption. The Peanut Marketing Agreement requirement for domestic edible peanuts is 15 parts per billion (ppb) total aflatoxins or less. Imported peanuts must meet the same requirement as domestic peanuts, and importers of peanuts must offer each lot of the product to USDA or a PAC-approved laboratory for inspection before introducing that lot into United States commerce.

**RESPONSIBILITIES:**

AMS intends to:

1. Continue to provide oversight to the PAC in the administration of the Marketing Agreement for peanuts to control the incidence and levels of total aflatoxins in domestically produced peanuts.
2. Monitor and inspect imported raw peanuts upon effective date of peanut import regulations.
3. Perform all aflatoxin assays using the official methods in the current ''Instruction Manual for Aflatoxin Testing'', United States Department of Agriculture, Agricultural Marketing Service, Science and Technology Division, Technical Services Branch.
4. Issue aflatoxin certificates as (1) ''negative'' if the level is not over 15 ppb; (2) number if the level is over 15 ppb.
5. Provide FDA with a copy of the certificate of total aflatoxins analysis and the name of the applicant on each lot, both domestic and imported, found to exceed 15 ppb total aflatoxins and the analysis certificate on any lot on request.

FDA Intends to:

1. Maintain its administrative guideline at 20 ppb on objective samples recognizing that good manufacturing practices remove significant quantities of unfit peanuts and that levels of total aflatoxins are reduced by heating.
2. Not object to the offering of lots of peanuts to processors where certificates show levels of total aflatoxins above 25 ppb but to examine routinely finished products from such lots. Such lots of raw peanuts may be subject to action in cases where there is not a reasonable assurance that the finished product will contain no more than 20 ppb total aflatoxins.

AMS and FDA mutually agree to:

1. Designate a person to serve as a central contact to whom communications dealing with this agreement or matters affected thereby may be first referred for attention.

For the Food and Drug Administration: Director, Division of Programs and Enforcement Policy, HFS–305 (currently Terry C. Troxell, Ph.D.) Office of Plant and Dairy Foods and Beverages Center for Food Safety and Applied Nutrition, 200 C. Street S.W., Washington, D.C. 20204, Telephone: 202–205–5321

For the Agricultural Marketing Service: Director, Science and Technology Division (currently William J. Franks, Jr.) USDA, AMS 14th & Independence Avenue, S.W. Washington, D.C. 20090–6456, Telephone: 202–720–6496.

2. Maintain close working relations with each other, both in headquarters as well as in the field.
3. Work with industry toward greater efficiency in connection with improvement of the testing program.

BASIS OF COOPERATION—This Memorandum of Understanding defines in general terms the basis on which the parties concerned will cooperate, and does not constitute a financial obligation to serve as a basis for expenditures. Each party will handle and expend its own funds. Any and all expenditures from Federal funds in the Department of Agriculture made in conformity with the plans outlined in the Memorandum of Understanding must be in accord with Department rules and regulations and in each instance based upon appropriate finance papers. Expenditures made by FDA will be in accord with its rules and regulations.

Nothing in this agreement modifies other existing agreements, nor does it preclude entering into separate agreements setting forth procedures for special programs that can be handled more efficiently and expeditiously by such special agreement.

The responsibilities assumed by the cooperating parties under this Memorandum of Understanding are contingent upon funds being available from which expenditures legally may be made.

DURATION—This agreement will continue in force indefinitely. It may be amended or terminated by mutual consent of the parties in writing. It may be terminated by either party upon 30 days' notice in writing to the other party.

This agreement is hereby approved for the Agricultural Marketing Service.

Done at Washington, D.C. on October 1, 1997,
Barbara A. Chaffey,
Deputy Administrator, Marketing Programs
Agricultural Marketing Service.

This agreement is hereby approved for the Food and Drug Administration:
Done at Washington, D.C. on October 1, 1997,
Ronald G. Chesemore,
Associate Commissioner for Regulatory Affairs.

Agreement No.
225–96–2002
Revision 1
12–25–MU–334
Revision 1

**Memorandum of Understanding Between the Science and Technology Division of the Agricultural Marketing Service, United States Department of Agriculture and the Food and Drug Administration, Department of Health and Human Service**

| | |
|---|---|
| PROJECT | Voluntary aflatoxin testing of imported in-shell Brazil nuts |
| LEADERS | Administrator, Agricultural Marketing Service (AMS), United States Department of Agriculture (USDA) and Associate Commissioner for Regulatory Affairs, Food and Drug Administration (FDA), Department of Health and Human Services (HHS) |
| LOCATIONS | Blakely, Georgia, and Dothan, Alabama |
| HEADQUARTERS | Washington, DC |
| EFFECTIVE DATE | October 1, 1997 |
| LEGAL AUTHORITY | The Agricultural Marketing Act of 1946, and the Federal Food, Drug, and Cosmetic Act of 1938, as Amended |
| REVISION | This is a revision of and shall supersede Memorandum of Understanding, FDA–225–96–2002, effective October 1, 1995, between FDA and AMS. |
| ORGANIZATION | The organization shall consist of the leaders, qualified analytical chemists and physical science technicians provided and supervised by the AMS Aflatoxin Supervisor, and technical contacts provided and supervised by the Chief, Technical Services Branch, Science and Technology Division (S&TD), AMS. |
| BACKGROUND | Aflatoxins have been shown to cause cancer in certain laboratory animals. Aflatoxins are produced by the mold *Aspergillus flavus* and may contaminate various kinds of foods, including Brazil nuts. FDA and AMS have cooperated with United States importers in a program for sampling and aflatoxin testing of imported Brazil nuts. Neither AMS nor FDA has a formal agreement with the Brazil nut importers. Under this voluntary program, importers of Brazil nuts offer each lot of the product to USDA for inspection prior to its introduction into United States commerce. USDA is responsible for sampling and testing each lot for total aflatoxins in accordance with procedures prescribed by FDA and for issuing an analysis certificate for each lot tested. |

**RESPONSIBILITIES:**

AMS intends to:

1. Draw samples in accordance with the following schedule:

TABLE I.—LOTS PACKED IN CONTAINERS WEIGHING 50 LBS. OR LESS

| Number of bags in lot | Number of bags sampled | Total pounds in sample | Approximate no. of nuts |
|---|---|---|---|
| 500 or less | 60 | 20 | 1,000 |
| 501–1,800 | 120 | 40 | 2,000 |
| 1,801–4,500 | 180 | 60 | 3,000 |

TABLE II.—LOTS PACKED IN CONTAINERS WEIGHING 51 TO 120 LBS.

| Number of bags in lot | Number of bags sampled | Total pounds in sample | Approximate no. of nuts |
|---|---|---|---|
| 200 or less | 20 | 20 | 1,000 |
| 201–800 | 40 | 40 | 2,000 |
| 801–2,000 | 60 | 60 | 3,000 |

2. Perform aflatoxin assay.

(a) Shell and Kernel Analysis.

The entire sample of shells and kernels will be ground in a vertical cutter mixer. A well-mixed portion of the ground composite will be assayed chemically for total aflatoxins, using the BF method as described in the book of Official Methods of Analysis of AOAC International, 16th ed., Vol. II, Sec. 49.2.09. The total aflatoxins level will be calculated on the basis of the nut kernel, assuming the kernel constitutes half the weight of the total in-shell nut.

(b) Kernel Analysis

The entire sample is individually shelled. Those kernels that have an obviously inedible appearance will be discarded. The remaining kernels will be composited and ground with the addition of an inert grinding aid. A well-mixed portion of the ground composite will be assayed as described in paragraph (a) above.

3. Report Results

(a) A separate analysis certificate will be issued for each lot. Appropriate identification marks will be shown on each certificate so that the report can be related to the specific lot sampled.

(b) Provide appropriate FDA District Office the results of aflatoxin analysis for lots that may be subject to action under the Food, Drug, and Cosmetic Act and

analysis certificate on any lot upon request.

FDA intends to:

1. Notify AMS of the criteria FDA will use concerning total aflatoxins levels in lots to determine whether they may be subject to action under the Food, Drug, and Cosmetic Act.
2. Review results of aflatoxin analysis for lots provided by AMS to determine whether they may be subject to action under the Food, Drug, and Cosmetic Act.

AMS and FDA mutually agree to:

1. Designate a person to serve as a central contact to whom communications dealing with this agreement or matters affected thereby may be first referred for attention.

For the Food and Drug Administration: Director, Division of Programs and Enforcement Policy, HFS–305 (currently Terry C. Troxell, Ph.D.), Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, 200 C. Street S.W. Washington, D.C. 20204, Telephone: 202–205–5321

For the Agricultural Marketing Service: Director, Science and Technology Division (currently William J. Franks, Jr.) USDA, AMS 14th & Independence Avenue, S.W. Washington, D.C. 20090–6456, Telephone: 202–720–6496.

2. Maintain close working relations with each other, both in headquarters as well as in the field.
3. Work with industry toward greater efficiency in connection with improvement of the testing program.

BASIS OF COOPERATION—This Memorandum of Understanding defines in general terms the basis on which the parties concerned will cooperate, and does not constitute a financial obligation to serve as a basis for expenditures. Each party will handle and expend its own funds. Any and all expenditures from Federal funds in the Department of Agriculture made in conformity with the plans outlined in the Memorandum of Understanding must be in accord with Department rules and regulations and in each instance based upon appropriate finance papers. Expenditures made by FDA will be in accord with its rules and regulations.

Nothing in this agreement modifies other existing agreements, nor does it preclude entering into separate agreements setting forth procedures for special programs that can be handled more efficiently and expeditiously by such special agreement.

The responsibilities assumed by the cooperating parties under this Memorandum of Understanding are contingent upon funds being available from which expenditures legally may be made.

DURATION—This agreement will continue in force indefinitely. It may be amended or terminated by mutual consent of the parties in writing. It may be terminated by either party upon 30 days' notice in writing to the other party.

This agreement is hereby approved for the Agricultural Marketing Service.

Done at Washington, D.C. on October 1, 1997,

Barbara A. Chaffey,

Deputy Administrator, Marketing Programs Agricultural Marketing Service.

This agreement is hereby approved for the Food and Drug Administration:

Done at Washington, D.C. on October 1, 1997,

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

Agreement No.
225–96–2003
Revision 1
12–25–MU–336
Revision 1

**Memorandum of Understanding between the Science and Technology Division of the Agricultural Marketing Service, United States Department of Agriculture and the Food and Drug Administration Department of Health and Human Services**

PROJECT ..... Voluntary aflatoxin testing of imported in-shell pistachio nuts

LEADERS ..... Administrator, Agricultural Marketing Service (AMS), United States Department of Agriculture (USDA) and Associate Commissioner for Regulatory Affairs, Food and Drug Administration (FDA), Department of Health and Human Services (HHS)

LOCATIONS ..... Blakely, Georgia, and Dothan, Alabama

HEADQUARTERS ..... Washington, DC

EFFECTIVE DATE ..... October 1, 1997

LEGAL AUTHORITY ..... The Agricultural Marketing Act of 1946, and the Federal Food, Drug, and Cosmetic Act of 1938, as Amended

REVISION ..... This is a revision of and shall supersede Memorandum of Understanding, FDA 225–96–2003, effective October 1, 1995, between FDA and AMS.

ORGANIZATION ..... The organization shall consist of the leaders, qualified analytical chemists and physical science technicians provided and supervised by the AMS Aflatoxin Supervisor, and technical contacts provided and supervised by the Chief, Technical Services Branch, Science and Technology Division (S&TD), AMS.

BACKGROUND ..... Aflatoxins have been shown to cause cancer in certain laboratory animals. Aflatoxins are produced by the mold Aspergillus flavus and may contaminate various kinds of foods, including pistachio nuts. FDA and AMS have cooperated with United States importers in a program for sampling and aflatoxin testing of imported pistachio nuts. Neither AMS nor FDA has a formal agreement with the pistachio nut importers. The program is conducted on a voluntary basis whereby importers of pistachio nuts offer each lot of the product to USDA for inspection before introducing that lot into United States commerce. USDA is responsible for sampling and testing each lot for total aflatoxins in accordance with procedures prescribed by FDA and for issuing an analysis certificate for each lot tested.

**RESPONSIBILITIES:**

AMS intends to:

1. Draw samples in accordance with the following schedule:

TABLE I.

| Total weight of lot | Percent of containers sampled | Total sample weight |
|---|---|---|
| 75,000 lb or less | Minimum of 20% | Shelled–25 lb In-shell–50 lb |

TABLE I.—Continued

| Total weight of lot | Percent of containers sampled | Total sample weight |
|---|---|---|
| More than 75,000 lb to 150,000 lb | Minimum of 20% | Shelled–50 lb In-shell–100lb |

For lots with total weight greater than 150,000 pounds, a sample will be selected from 20 percent of the containers in the lot and consist of 25 lb of shelled nuts or 50 lb of in-shell nuts for each multiple of 75,000 lb (e.g., 150,000 to 225,000 lb requires a 3-fold sample of 75 lb shelled or 150 lb of in-shell nuts).

2. Perform aflatoxin assay.

(a) In-Shell Lots.

The entire sample of shells and kernels will be ground in a vertical cutter mixer. A well-mixed portion of the ground composite will be assayed chemically for total aflatoxins, using either of the two methods for aflatoxin assay in pistachios described in the book of Official Methods of Analysis of AOAC International, 16th ed., Vol. II, Sec. 49.2.23. The aflatoxin level will be calculated on a kernel weight basis.

(b) Shelled Lots

The entire sample shall be ground, including those kernels which have an obvious inedible appearance. A well-mixed portion of the ground composite will be assayed as in paragraph 2.(a) above.

3. Report Results

(a) A separate analysis certificate will be issued for each lot. Appropriate identification marks will be shown on each certificate so that the report can be related to the specific lot sampled.

(b) Provide appropriate FDA District Office the results of aflatoxin analysis for lots that may be subject to action under the Food, Drug, and Cosmetic Act and analysis certificate on any lot upon request.

FDA intends to:

1. Notify AMS of the criteria FDA will use concerning total aflatoxins levels in lots to determine whether they may be subject to action under the Food, Drug, and Cosmetic Act.
2. Review results of aflatoxin analysis for lots provided by AMS to determine whether they may be subject to action under the Food, Drug, and Cosmetic Act.

AMS and FDA mutually agree to:

1. Designate a person to serve as a central contact to whom communications dealing with this agreement or matters affected thereby may be first referred for attention.

For the Food and Drug Administration: Director, Division of Programs and Enforcement Policy, HFS–305 (currently Terry C. Troxell, Ph.D.) Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition 200 C. Street S.W. Washington, D.C. 20204 Telephone: 202–205–5321

For the Agricultural Marketing Service: Director, Science and Technology Division (currently William J. Franks, Jr.) USDA, AMS 14th & Independence Avenue, S.W. Washington, D.C. 20090–6456, Telephone: 202–720–6496.

2. Maintain close working relations with each other, both in headquarters as well as in the field.
3. Work with industry toward greater efficiency in connection with improvement of the testing program.

BASIS OF COOPERATION—This Memorandum of Understanding defines in general terms the basis on which the parties concerned will cooperate, and does not constitute a financial obligation to serve as a basis for expenditures. Each party will handle and expend its own funds. Any and all expenditures from Federal funds in the Department of Agriculture made in conformity with the plans outlined in the Memorandum of Understanding must be in accord with Department rules and regulations and in each instance based upon appropriate finance papers. Expenditures made by FDA will be in accord with its rules and regulations.

Nothing in this agreement modifies other existing agreements, nor does it preclude entering into separate agreements setting forth procedures for special programs that can be handled more efficiently and expeditiously by such special agreement.

The responsibilities assumed by the cooperating parties under this Memorandum of Understanding are contingent upon funds being available from which expenditures legally may be made.

DURATION—This agreement will continue in force indefinitely. It may be amended or terminated by mutual consent of the parties in writing. It may be terminated by either party upon 30 days' notice in writing to the other party.

This agreement is hereby approved for the Agricultural Marketing Service.

Done at Washington, D.C. on October 1, 1997,

Barbara A. Chaffey,

Deputy Administrator, Marketing Programs Agricultural Marketing Service.

This agreement is hereby approved for the Food and Drug Administration:

Done at Washington, D.C. on October 1, 1997,

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 97–31809 Filed 12–4–97; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 96N–0496]**

### 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 ''Reporting and Recordkeeping Requirements for Manufacturers and Distributors of Electronic Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 28, 1997 (62 FR 45665), 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 0910–0025. The approval expires on October 31, 2000.

Dated: November 27, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–31943 Filed 12–4–97; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; 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 National Heart, Lung, and Blood Institute Special Emphasis Panel (SEP) meetings:

*Name of SEP:* Coronary Stent Angioplasty: Factors Affecting Restenosis (Telephone Conference Call).

*Date:* January 6, 1998.

*Time:* 9:00 a.m.

*Place:* 6701 Rockledge Drive, Room 7214, Bethesda, Maryland 20892.

*Contact Person:* C. James Scheirer, Ph.D., Two Rockledge Center, Room 7220, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0266.

*Purpose/Agenda:* To review and evaluate grant applications.

*Name of SEP:* Specialized Centers of Research in Acute Lung Injury.

*Date:* January 7–8, 1998.

*Time:* 8:00 a.m.

*Place:* Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, Maryland 20815.

*Contact Person:* Anne P. Clark, Ph.D., Two Rockledge Center, Room 7186, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0280.

*Purpose/Agenda:* To review and evaluate grant applications.

*Name of SEP:* Specialized Centers of Research in Neurobiology of Sleep and Sleep Apnea.