and analyses to justify a hearing, other comments, and a grant or denial of a hearing, are contained in 21 CFR 314.200 (except that the limitations imposed by 21 CFR 314.200(d)(1) and (d)(2) do not apply) and in 21 CFR part 12.

The failure of the applicant to file a timely, written notice of appearance and request for a hearing, as required by 21 CFR 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed, and a waiver of any contentions concerning the legal status of that person's drug products. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. In order to raise a genuine and substantial issue of fact justifying a hearing on the issue of whether the application contains untrue statements, the applicant must specifically identify new evidence that supports its position. Mere allegations and denials, arguments by counsel, or the unsupported articulation of possible alternate inferences will not suffice to obtain a hearing. See 21 CFR 12.24(b)(2); see also *Cooper Laboratories, Inc.* v. *Commissioner, Federal Food and Drug Administration,* 501 F.2d 772, 785 (D.C. Cir. 1974); *Pineapple Growers Ass'n* v. *Food and Drug Administration,* 673 F.2d 1083–1085 (9th Cir. 1982); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 620–621 (1973).

In order to obtain a hearing, the new evidence must do more than reaffirm the applicant's belief that the information in the application is true. As explained above, the Director's conclusion that the applications contain an untrue statement of material facts is based on: (1) Selective reporting of stability data without justification, (2) omission of failing stability test results, and (3) actual conflicts between stability data reported to FDA and stability data retained by the firm.

In order to raise an issue of fact about whether the application contains truthful information, the applicant's evidence should be directed toward the basis of the Director's conclusion that the statements in the application are untrue. The applicant's failure to present evidence identifying a genuine and substantial issue of fact with respect to the Director's conclusion that the applications listed in this notice contain untrue statements of material fact, leaves the basis for the conclusion intact, and will result in the denial of a hearing on those issues.

In addition, the submission of truthful information to replace untrue statements will not result in a finding that the previously identified untrue statements are no longer material. If corrective information could nullify the materiality of untrue statements, then applicants could simply correct all untrue statements as soon as they were discovered.

Should a hearing be held on these issues, the participants requesting the hearing will bear the burden of proof with respect to whether the applications contain untrue statements of material fact and, ultimately, whether the drugs that are the subject of the applications listed in this notice have been shown to be safe and effective (21 CFR 12.87(d)).

If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of the applications, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request the hearing, making findings and conclusions, and denying a hearing.

Section 505(j)(6)(C) of the act requires that FDA remove from its approved product list contained in FDA's publication the Orange Book any drug that was withdrawn for grounds described in the first sentence of section 505(e) of the act. If the agency determines that withdrawal of the drugs subject to this notice is appropriate, FDA will announce the removal of the relevant drugs from the list in the **Federal Register** notice announcing the withdrawal of approval of the drugs.

All submissions pursuant to this notice of opportunity for hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: June 13, 1995.

Murry A. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 95–15539 Filed 6–23–95; 8:45 am]

BILLING CODE 4160–01–P

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of a 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 Heart, Lung, and Blood Special Emphasis Panel (SEP) meeting:

Name of SEP: Lung Specific Drug Delivery Systems for Tuberculosis Treatment.

Date: July 18, 1995.

Time: 8:00 a.m.

Place: Hyatt Regency, Bethesda, Maryland.

Contact Person: Carl A. Ohata, Ph.D., 6701 Rockledge Drive, Room 7198, Bethesda, Maryland 20892–7924, (301) 435–0297.

Purpose/Agenda: To review and evaluate grant applications.

The meeting 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 would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: June 19, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–15561 Filed 6–23–95; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Dental Research; 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 Institute of Dental Research Special Emphasis Panel (SEP) meetings:

Name of SEP: National Institute of Dental Research Special Emphasis Panel-Delivery System for Periodontal Tissue Growth Factors (Telephone Review).

Dates: July 6, 1995.

Time: 12:00 noon.

Place: Natcher Building, Rm. 4AN–44F, National Institutes of Health, Bethesda, MD 20892.

Contact Person: Dr. George Hausch, Chief, Review Section, 4500 Center Drive, Natcher Building, Room 4AN–44F, Bethesda, MD 20892, (301) 594–2372.

Purpose/Agenda: To evaluate and review grant applications and/or contact proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel-PT Intervention-An Effective Change Agent in TMD (Telephone Conference).