announcement to new officers and directors of Dell; to every employee of Dell whose responsibilities include acting as Dell's designated representative to any standard-setting organization, group or similar body of which respondent is a member; and to each standard-setting organization of which Dell is a member. Dell must also identify to each standard-setting organization it joins the name of the person who will serve as its designated representative to the standard-setting organization.

Part VII requires Dell to file compliance reports for five years.

Donald S. Clark,

Secretary.

Dissenting Statement of Commissioner Mary L. Azcuenaga in Deli Computer Corp.

[File No. 931–0097]

Today, the Commission accepts for public comment a consent order that prohibits Dell Computer Corp. (''Dell'') from attempting to enforce its ''′481 patent'' against anyone ''using or applying VL-bus in its manufacture of computer equipment,'' because Dell failed to warn the Video Electronics Standards Association (''VESA'') of Dell's intellectual property rights when VESA adopted its computer local bus design standard (''VL-bus''). Because the complain does not allege and the evidence does not support a violation of Section 5 of the FTC Act under any established theory of law, and because under any novel theory the competitive implications of the conduct alleged remain unclear, I dissent.

VESA is a private standard-setting association, the members of which include both computer hardware and software manufacturers. In early 1992, a VESA committee developed a proposed standard for a computer bus to carry information between the central processing unit and the peripheral devices of a computer. In August 1992, VESA members, including Dell, voted to approve the proposed standard. The trade association's ballot required each member's authorized representative to VESA to sign a statement that ''to the best of my knowledge,'' the proposal did not infringe the member company's intellectual property rights. Dell subsequently asserted that implementation of the VL-bus by others infringed Dell's patent rights.

One antitrust theory might be that Dell intentionally mislead VESA regarding the scope of its patent rights; that VESA, relying on Dell's misrepresentations, adopted a standard that conflicted with Dell's rights; and that as a result of the standard, Dell acquired market power. No evidence supports a finding of such intentional conduct, and the allegations in the complaint do not seem sufficient to support a finding of liability on the basis of this theory. I welcome comment on the factual showing that would be necessary and appropriate under this theory.

Another Section 5 theory might be that by participating in a private trade association's standard-setting activities, a firm assumes an affirmative duty to identify the boundaries of its intellectual property rights and to warn the association of any potential conflicts. Alternatively, the Commission might impose such a duty only if a firm returns a ballot with a certification like VESA's, so that a firm could escape antitrust exposure by simply not voting.

Adoption of this novel theory of liability may affect a range of standard-setting organizations. In creating a new antitrust-based duty of care for participants in the voluntary standard setting process, a host of questions need to be resolved. I welcome public comment on the appropriate nature and scope of any such duty, and I look forward to reassessing the case at the end of the comment period.

[FR Doc. 95–28459 Filed 11–21–95; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings 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.

MEETINGS: The following advisory committee meetings are announced:

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. December 5, 1995, 1:30 p.m., Food and Drug Administration, Bldg. 29, conference room 121, 8800 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. This meeting 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. Closed committee deliberations, 1:30 p.m. to 4 p.m.; open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; Nancy Cherry or Sandy Salins, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person.

Closed committee deliberations. The committee will review trade secret and/or confidential commercial information relevant to current and pending products. This portion of the meeting will be closed to permit discussion of this information (5 USC 552b(c)(4)).

Radiological Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. December 11, 1995, 8:30 a.m., Holiday Inn—Gaithersburg, Goshen Room, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 and reference the FDA panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Gloria Williams, Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:45 a.m., unless public participation does not last that long; open committee

discussion, 9:45 a.m. to 12:30 p.m.; closed committee deliberations, 12:30 p.m. to 1:30 p.m.; open committee discussion, 1:30 p.m. to 4:30 p.m.; John C. Monahan, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Radiological Devices Panel, code 12526.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before December 6, 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.

Open committee discussion. The committee will discuss general issues related to a premarket approval application for an ultrasound imaging device indicated for use on the breast in women with abnormalities based on prior mammography and/or physical examination. This device will be used to further evaluate solid mass characteristics in order to reduce the number of biopsies.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Anesthetic and Life Support Drugs Advisory Committee

Date, time, and place. December 11 and 12, 1995, 8:30 a.m., Holiday Inn, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, December 11, 1995, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; open committee discussion, December 12, 1995, 8:30 a.m. to 11 a.m.; closed committee deliberations, 11 a.m. to 1 p.m.; Stephen P. Pollitt, 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 Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Anesthetic and Life Support Drugs Advisory Committee, code 12529.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the field of anesthesiology and surgery.

Agenda—Open public hearing. Interested persons may present data information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before December 1, 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.

Open committee discussion. The committee will discuss the new drug application (NDA) 20–533, Naropin® , Astra Laboratories, for use as a local anesthetic and a report of the postmarket surveillance of NDA 27–428, Oralet®, Anesta.

Closed committee deliberations. On December 12, 1995, the committee will review trade secret and/or confidential commercial information. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Blood Products Advisory Committee

Date, time, and place. December 14 and 15, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open committee discussion, December 14, 1995, 8 a.m. to 8:40 a.m.; open public hearing, 8:40 a.m. to 9:10 a.m., unless public participation does not last that long; open committee discussion, 9:10 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 3:30 p.m.; open public hearing, 3:30 p.m. to 4 p.m., unless public participation does not last that long; open committee discussion, 4 p.m. to 5 p.m.; open committee discussion, December 15, 1995, 8 a.m. to 10:30 a.m.; open public hearing, 10:30 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 2 p.m.; closed committee deliberations, 2 p.m. to 3 p.m.; Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–6700, FAX 301–594–6764, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area) Blood Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before December 8, 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.

Open committee discussion. On the morning of December 14, 1995, the committee will hear agency updates on Creutzfeldt-Jakob Disease and blood safety, and Human Immune Deficiency Virus, Type 1 (HIV–1) antigen screening of donors; review the report of the FDA/Health Resources Services Administration contract study of the Tissue Procurement and Distribution System in the United States, and hear scientific presentations on testing for Chagas disease (infection with *Trypanosoma cruzi*) in blood donors. In the afternoon, the committee will hear a summary of the Workshop on Cord Blood Derived Hematopoietic Stem Cells and presentation on Peripheral Blood Derived Hematopoietic Stem Cell Products Intended for Transfusion. A draft document for discussion concerning the application of current statutory authorities to peripheral blood hematopoietic stem cell products intended for transfusion will be made available. On the morning of December 15, 1995, the committee will review and make recommendations on issues related to respiratory syncytial virus immune globulin intravenous, MedImmune. In the afternoon, the committee will review and discuss the site visit reports of the Laboratories of Molecular Virology and

Immunochemistry, Division of Transfusion Transmitted Diseases.

Closed committee deliberations. The committee will discuss the intramural scientific program. This portion of the meeting will be closed to prevent disclosure of personal information concerning individuals associated with the research program, disclosure of which would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

Each public advisory committee meeting listed above 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. The dates and times reserved for the separate 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.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

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: November 14, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–28521 Filed 11–21–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Meeting of the Advisory Committee to the Director, NIH

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Advisory Committee to the Director, NIH, December 7, 1995, Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 8:30 a.m. to adjournment. The topics proposed for discussion include (1) Report from the Recombinant DNA Ad Hoc Committee; (2) Report and Recommendations from the Panel to Assesses the NIH Investment in Research on Gene Therapy; (3) Report from the Economics Roundtable; (4) Status Report from the Clinical Research Panel; and (5) Preliminary Report on the Study of Options Regarding the Clinical Center. Attendance by the public will be limited to space available.

Ms. Janice Ramsden, Program Assistant, Office of the Deputy Director, National Institutes of Health, 1 Center