Evaluation and Research (HFD–320), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–827–0072, FAX 301–594–2202;

Leslie Zeck, Parenteral Drug Association, 7500 Old Georgetown Rd., suite 620, Bethesda, MD 20814, 301–986–0293, FAX 301–986–0296, e-mail: http://www.pda.org;

Alice E. Till, Pharmaceutical Research and Manufacturers of America, 1100 15th St. NW., Washington, DC 20005, 202–835–3400, FAX 202–835–3597, e-mail: http://www.phrma.org; or

Steve Bende, Generic Pharmaceutical Association, 1620 I St. NW., suite 800, Washington, DC 20006, 202–833–9070, FAX 202–833–9612, e-mail: http://www.genericaccess.com.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Who Should Attend?

This announcement is directed towards professionals involved in the manufacture, control, and regulation of APIs who will benefit from this training, including: Process/production engineers, quality assurance/quality control and regulatory affairs professionals, auditors, agents, brokers, traders, distributors, repackers and relabelers of APIs, consultants, regulatory investigators and GMP compliance officials, and reviewing chemists. Other entities or individuals may also be interested in attending.

B. Where and When Will These Workshops Be Held?

TABLE 1.—WORKSHOP LOCATIONS AND DATES

Workshop Address	Date and Local Time
Illinois: The Allerton Crowne Plaza, 701 North Michigan Ave., Chicago, IL	October 22 to 24, 2001, from 9 a.m. to 5 p.m.
New Jersey: Hyatt Regency Princeton, 102 Carnegie Center, Princeton, NJ	November 7 to 9, 2001, from 9 a.m. to 5 p.m.
California: The Sutton Place Hotel, 4500 MacArthur Blvd., Newport Beach, CA	February 25 to 27, 2002, from 9 a.m. to 5 p.m.
Puerto Rico: Caribe Hilton San Juan, Los Rosales St., San Geronimo Ground,San Juan, PR	April 8 to 10, 2002, from 9 a.m. to 5 p.m.

C. How Can I Participate?

You can participate in person. Anyone interested in the API workshops can register through any of the information contacts (addresses above).

D. Is There a Registration Fee for This Workshop?

Yes, a registration fee of $995 is required for this workshop. This registration fee includes workshop reference materials, lunch on each day, and a networking reception on day 1. Government employees qualify for a discounted rate of $395.

E. How Can I Get Additional Information, Including Copies of This Document or Other Related Documents?

Submit written requests for single copies of the Q7A guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist the office in processing your requests. Once the notice of availability is announced in a future issue of the **Federal Register**, those with electronic access will be able to obtain electronic copies of the guidance document on the Internet at three locations: http://www.fda.gov/cder/guidance/index.htm; http://www.emea.eu.int/pdfs/human/ich/410600en.pdf; or http://www.ifpma.org/ich5q.html#gmp. The notice of participation form, information about the workshops, and other related documents are available from any of the information contacts (addresses above) or from the Internet at http://www.fda.gov/cder/calendar.

II. Background Information

A. Why is FDA Cosponsoring These Workshops?

FDA is cosponsoring these 3-day workshops to provide training of FDA personnel alongside industry participants on the ICH Q7A CGMP guidance for APIs. This is the first CGMP guidance developed jointly by regulators and industry and is intended for use worldwide. It affects manufacturers who manufacturer in, or intend to supply into, the ICH regions (United States, Europe, Japan).

B. What Will Be Covered?

FDA participation in these workshops will provide a regulatory perspective on the critical topic of the ICH guidance ''Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.'' Attendees will hear about the intent of the Expert Working Group that developed the Q7A guidance and learn how to interpret and apply the Q7A guidance, including special sections on APIs manufactured by cell culture/fermentation, and APIs for use in clinical trials.

Dated: September 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23804 Filed 9–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal 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: Cardiovascular and Renal Drugs Advisory Committee.

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

Date and Time: The meeting will be held on October 11, 2001, from 9 a.m. to 5 p.m.

Location: National Institutes of Health, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Contact: Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, Woodmont II Bldg., 1451 Rockville Pike, Rockville, MD 20752, 419–259–6211, or John Treacy or Jayne E. Peterson , 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug applications (NDA) 20–665

(capsules) and NDA 21–283 (tablets) Diovan® (valsartan), Novartis Pharmaceuticals Corp., for the treatment of patients with heart failure.

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 October 5, 2001. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. on October 11, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 5, 2001, 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.

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

Dated: September 18, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–23749 Filed 9–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0397]

Transportation Safety and Potentially Sedating or Impairing Medications; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to gather data on the potential public health consequences related to sedating or impairing medications. This meeting will be jointly sponsored with the National Transportation Safety Board (NTSB). The meeting will be held to determine what data are available to define the role of sedating or impairing medications in accidents and related injuries, how the potential for medications to cause impairment might be best assessed, and how this risk would be most effectively communicated to the public.

DATES: The meeting will be held on November 14, 2001, from 8 a.m. to 5 p.m. and November 15, 2001, from 8 a.m. to 4 p.m. Persons desiring to make oral presentations during the meeting must register by October 17, 2001. Submit written or electronic comments by December 17, 2001.

ADDRESSES: The public meeting will be held at the National Transportation Safety Board (NTSB) Board Room, 429 L'Enfant Plaza, SW., Washington, DC 20594. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

Registration: Submit registration information by close of business on October 17, 2001, electronically at http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm. Once on this Internet site, select Docket No. 01N–0397 and follow the directions. Submit registration information by mail to Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Lee Lemley or Anne M Food and Drug Administration,. Henig, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20857, 301–594–6779, e-mail: lemleyl@cder.fda.gov or heniga@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background Information

Why is FDA/NTSB holding this meeting?

FDA/NTSB is holding this joint meeting in response to NTSB Safety Recommendation I–00–5, requesting that FDA (1) Establish a clear, consistent, easily recognizable warning label for all prescription and over-the-counter medications that may interfere with an individual's ability to operate a vehicle and (2) require that the label be prominently displayed on all packaging of such medications.

On what issues does FDA seek comment?

- What data are available to show that sedating or impairing medications contribute to accidents?
- If data are available, can the public health impact of any such effect be delineated? What type of testing would best define the potential for a medication to contribute to accidents? Are there validated test methods for assessing the degree of risk associated with the use of medications that are sedating or impairing?
- What would be the most effective manner of communicating the risk of performance impairment (e.g., labeling, pictogram, educational programs, or other manner of communication)?
- What is the experience of other institutions (local, national, and international; public and private) in assessing, communicating, and preventing the risk of sedating or impairing medications in vehicle operators? How are currently applicable laws and regulations enforced?

II. Registration and Requests to Make Oral Presentations

If you would like to make an oral presentation during the meeting, you must register by close of business on October 17, 2001, either electronically or by mail (information above). There is no registration fee, but you must register. You must provide your name, title, business affiliation (if applicable), address, telephone number, fax number, e-mail address, and the type of organization you represent (e.g., industry, consumer organization). Registered persons should check in before the meeting. Persons requiring a sign language interpreter or other special accommodations should notify Lee Lemley or Anne M. Henig at 301–594–6779 by October 31, 2001.

If you are making an oral presentation during the meeting, you must indicate this on your registration form and submit: (1) A brief written statement of the general nature of the views you wish to present and (2) the names and addresses of all persons who will participate in the presentation.

Depending on the number of people who register to make presentations, we will limit the time allotted for each presentation (from 3 to 5 minutes). It is anticipated that, during the meeting, persons attending the meeting will have the opportunity to ask questions through question cards that will be handed out.

III. Comments

Interested persons may submit to the Dockets Management Branch (addresses above) written or electronic comments regarding the topics addressed at the public meeting by December 17, 2001. Two copies of any written 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 may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Transcripts

You may access a copy of the transcript on the FDA Internet site at http://www.fda.gov, request a transcript of the meeting from the Freedom of Information Office (HFI–35), Food and