(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

Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 20 working days after the meeting, at a cost of 10 cents per page, or examine a transcript of the meeting after December 17, 2001, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23805 Filed 9–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1538]

Draft Guidance for Industry; Electronic Records; Electronic Signatures, Validation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation.'' The draft guidance describes the agency's current thinking on issues pertaining to validating computer systems subject to part 11 (21 CFR part 11) requirements, to ensure that electronic records and electronic signatures are trustworthy, reliable, and compatible with FDA's public health responsibilities. Such validation is a requirement of part 11 of title 21 of the Code of Federal Regulations.

DATES: Submit written or electronic comments on the draft guidance by Decmeber 24, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Compliance Information and Quality Assurance (HFC–240), Office of Enforcement, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, room 1060, Rockville, MD 20852. Submit electronic comments to *http://www.FDA.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paul J. Motise, Office of Enforcement (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0383, e-mail: *pmotise@ora.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation.'' In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published a regulation providing criteria under which the agency considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper (''part 11''). The preamble to part 11 stated that the agency anticipated issuing supplemental guidance documents and would afford all interested parties the opportunity to comment on draft guidance documents. Therefore, FDA is making this draft guidance available for public comment.

The draft guidance addresses issues pertaining to the validation of computer systems used to create, modify, maintain, archive, retrieve, or transmit electronic records and electronic signatures subject to part 11. Part 11 requires such validation, and the guidance is intended to assist people who must meet this requirement; it may also assist FDA staff who apply part 11 to persons subject to the regulation.

The draft guidance provides specific information on key validation principles, and it addresses some frequently asked questions. However, it is not intended to cover everything that computer systems validation should encompass in the context of electronic record/signature systems. In addition to addressing key validation principles, the draft document discusses considerations regarding off the shelf software and the Internet.

By direct reference, this draft guidance incorporates definitions of terms contained in a companion draft guidance, ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms.'' Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of that companion draft document, and is offering the opportunity to comment on it, as well.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on validating computerized systems subject to part 11. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any 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. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ora/compliance_ref/Part11.*

Dated: August 23, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23698 Filed 9–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1543]

Draft Guidance for Industry; Electronic Records; Electronic Signatures, Glossary of Terms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms.'' The draft guidance defines terms that will be used in FDA's guidances that describe the agency's current thinking on principles and procedures for creating, modifying, maintaining, archiving, retrieving, and transmitting electronic records and electronic signatures in order to ensure that electronic records