

availability of a guidance for industry entitled "Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims." This guidance is intended to assist applicants in developing labeling for outcome claims for drugs that are indicated to treat hypertension. With few exceptions, current labeling for antihypertensive drugs includes only the information that these drugs are indicated to reduce blood pressure; the labeling does not include information on the clinical benefits related to cardiovascular outcomes expected from such blood pressure reduction. However, blood pressure control is well established as beneficial in preventing serious cardiovascular events, and inadequate treatment of hypertension is acknowledged as a significant public health problem. The Agency believes that the appropriate use of these drugs can be encouraged by making the connection between lower blood pressure and improved cardiovascular outcomes more explicit in labeling.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Devi Kozeli, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4183, Silver Spring, MD 20993-0002, 301-796-1128.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled "Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims." The intent of the guidance is to provide common labeling for antihypertensive drugs except where differences are clearly supported by clinical data. With publication of this guidance, applicants are encouraged to submit labeling

supplements containing the new language.

A draft guidance of the same title was announced in the **Federal Register** on March 13, 2008 (73 FR 13546), and Docket No. FDA-2008-D-0150 was open for comments until May 12, 2008. Comments received from industry, professional societies, and consumer groups on the draft guidance were taken into consideration by FDA in finalizing this guidance. Throughout the guidance, the language has been condensed and simplified to be more concise and clear. A section has been added to clarify procedures for obtaining approval of new labeling and its applicability to advertising. The guidance describes how applicants can provide clinical evidence for any drugs they perceive to be missing from Table 1, Approved Drugs for Chronic Treatment of Hypertension, by submitting the information to the docket number listed in brackets in the heading of this document. The division will review the information and revise the guidance to include any new labeling changes supported by clinical data submitted to the docket.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on labeling for cardiovascular outcome claims for drugs to treat hypertension. 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. The Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in this guidance was approved under OMB control number 0910-0670.

##### **III. Comments**

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### **IV. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-5945 Filed 3-14-11; 8:45 am]

**BILLING CODE 4160-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. FDA-2009-D-0568]

##### **Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products." The guidance encourages manufacturers of medically necessary drug products (MNPs) and components to develop production plans in the event of an emergency that results in high absenteeism at one or more production facilities. The purpose of the guidance is to provide to industry considerations for developing plans for these types of emergencies, as well as to discuss the Center for Drug Evaluation and Research's (CDER's) intended approach to assist in avoiding drug product shortages that may have a negative impact on the national public health during such emergencies.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Thomas J. Christl, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3358, Silver Spring, MD 20993-0002, 301-796-2057.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products." The guidance encourages manufacturers of MNPs and components to develop production plans in the event of an emergency that results in high absenteeism at one or more production facilities. In particular, the guidance provides recommendations regarding considerations for the development and implementation of a production plan, including specific elements to include in such a plan. The guidance is intended for manufacturers of finished drug products as well as manufacturers of the raw materials necessary for manufacturing of an MNP.

The purpose of this guidance is to provide to industry considerations for developing plans for these types of emergencies, as well as to discuss CDER's intended approach to assist in avoiding shortages that may have a negative impact on the national public health during such emergencies. This guidance applies to manufacturers of drug and therapeutic biologic products regulated by CDER, and any components of those products. These considerations include, but are not limited to:

- General preparedness through employee education and immunization,
- Prioritization of manufactured products based on medical necessity,
- Developing training, manufacturing and laboratory contingencies for high absenteeism, and
- How to plan for returning to normal operations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on planning for the effects of high absenteeism to ensure availability of MNPs. 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 Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in this guidance were approved under OMB control number 0910-0675.

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-5949 Filed 3-14-11; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0002]

**Antiviral 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:* Antiviral 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 April 27, 2011, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings". Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8540, e-mail: [paul.tran@fda.hhs.gov](mailto:paul.tran@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On April 27, 2011, the committee will discuss a new drug application (NDA) 202-258, boceprevir (a hepatitis C virus protease inhibitor), manufactured by Merck & Co., Inc., with a proposed indication for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin (two medicines approved to treat chronic hepatitis C infection) in adult patients with compensated liver disease who are previously untreated or who have failed previous therapy. Compensated liver disease is a stage in which the liver is damaged but maintains ability to function.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the