withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ROCEPHIN (ceftriaxone sodium) Injection, 250mg, 500mg, 1g, 2g, and 10g base/vial, approved under NDA 050585, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been withdrawn from sale for reasons other than safety or effectiveness. ANDAs that refer to any of the products described in this notice may be approved by FDA as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for any of these drug products should be revised to meet current labeling for any of these drug products regulatory requirements for the approval this notice may be approved by FDA as

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on non-penicillin beta-lactam risk assessment. 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 statute 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. Electronic Access

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.


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, which is available at http://www.fda.gov/Drugs/GuidanceCompliance/GuidanceCompliance/default.htm or http://www.regulations.gov. Necessary Drug Products; Availability

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/GuidanceCompliance/ RegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

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 (MNP) 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 recommendations 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.