withdrawn from sale for reasons of safety or effectiveness.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 The "Discontinued Drug Product List" delineates, among other items, drug products that have been withdrawn from sale for reasons other than safety or effectiveness.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 standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5947 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–D–0104]

Draft Guidance for Industry on Non-Penicillin Beta-Lactam Risk Assessment: A CGMP Framework; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Non-Penicillin Beta-Lactam Risk Assessment: A CGMP Framework." This guidance describes the importance of implementing appropriate steps during the manufacturing process to prevent cross-contamination of finished pharmaceuticals and active pharmaceutical ingredients (APIs) with non-penicillin beta-lactam antibiotics. The draft guidance is intended to assist manufacturers in assessing whether separate facilities should be used based on the relative health risk of cross-reactivity.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 16, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm.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 request. The guidance may also be obtained by mail by calling CDER at 301–796–3400. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments concerning the draft 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Edwin Melendez, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4370, Silver Spring, MD 20993–0002, 301–796–3284.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Non-Penicillin Beta-Lactam Risk Assessment: A CGMP Framework." This draft guidance describes the importance of implementing appropriate steps during the manufacturing process to prevent cross-contamination of finished pharmaceuticals and APIs with non-penicillin beta-lactam antibiotics. It also provides information regarding the relative health risk of, and the potential for, cross-reactivity in the classes of sensitizing beta-lactams (penicillins and non-penicillin beta-lactams).

Drug cross-contamination is the contamination of one drug with one or more different drugs. Cross-contamination with non-penicillin beta-lactam drugs can initiate drug-induced hypersensitivity reactions, including anaphylaxis, an allergic reaction that may be a life-threatening event. One critical aspect of manufacturing non-penicillin beta-lactam drugs is preventing cross-contamination to reduce the potential for drug-induced, life-threatening allergic reactions. FDA is recommending that manufacturers establish appropriate separation and control systems designed to prevent the following types of cross-contamination: (1) Non-penicillin beta-lactam contamination in a non-beta-lactam product (*e.g.,* cefaclor in aspirin) and (2) non-penicillin beta-lactam contamination in another non-penicillin beta-lactam (*e.g.,* cephalexin in imipenem).

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

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.*

Dated: March 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5948 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–2008–D–0150]

Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims; 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 "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.