information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
806.10	666	1	666	10	6660

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN [1]

CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
806.20	90	1	90	10	900

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5916 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–P–0177]

Determination that ROCEPHIN (Ceftriaxone Sodium) Injection, 250 Milligrams, 500 Milligrams, 1 Gram, 2 Grams, and 10 Grams Base/Vial, Approved Under New Drug Application 050585, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined ROCEPHIN (ceftriaxone sodium) Injection, 250 milligrams (mg), 500mg, 1 gram (g), 2g, and 10g base/vial, approved under new drug application (NDA) 050585, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for any of these products if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6368, Silver Spring, MD 20993–0002, 301–796–3522.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ROCEPHIN (ceftriaxone sodium) Injection, 250mg, 500mg, 1g, 2g, and 10g base/vial, are the subject of NDA 050585 held by F. Hoffman-La Roche Ltd. (La Roche). ROCEPHIN (ceftriaxone sodium) is a semisynthetic cephalosporin antibiotic for intravenous or intramuscular administration and is indicated for the treatment of certain infections as described in the labeling. The drug products approved under NDA 050585 are currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Steven H. Sklar of Leydig, Voit & Mayer, Ltd., submitted a citizen petition dated April 3, 2009 (Docket No. FDA–2009–P–0177), under 21 CFR 10.30, requesting that FDA determine that ROCEPHIN (ceftriaxone sodium) Injection, 250mg, 500mg, 1g, 2g, and 10g base/vial, approved under NDA 050585, were withdrawn from sale for reasons other than safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that ROCEPHIN (ceftriaxone sodium) Injection, 250mg, 500mg, 1g, 2g, and 10g base/vial, approved under NDA 050585, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these products were withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of these products from sale. We have also independently evaluated the relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that any of these products were

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