



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0104]

Guidance for Industry on Non-Penicillin Beta-Lactam Drugs: A Current Good Manufacturing Practices Framework for Preventing Cross-Contamination; 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 “Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination.” This guidance describes the importance of implementing controls to prevent cross-contamination of finished pharmaceuticals and active pharmaceutical ingredients (APIs) with non-penicillin beta-lactams. This guidance also provides information regarding the relative health risk of, and the potential for, cross-reactivity in the classes of sensitizing beta-lactams (including both penicillins and non-penicillin beta-lactams), beta-lactamase inhibitors, and beta-lactam intermediates and derivatives. Finally, this guidance clarifies that manufacturers should generally utilize separate facilities for manufacture of non-penicillin beta-lactams because those compounds pose health risks associated with cross-reactivity.

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:

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10903 New Hampshire Ave.,
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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination." This guidance describes the importance of implementing controls to prevent cross-contamination of finished pharmaceuticals and APIs with non-penicillin beta-lactam drugs. This guidance also provides information regarding the relative health risk of, and the potential for, cross-reactivity in the classes of sensitizing beta-lactams (including both penicillins and non-penicillin beta-lactams). Finally, this guidance clarifies that manufacturers should generally utilize separate facilities for

manufacture of non-penicillin beta-lactams because those compounds pose health risks associated with cross-reactivity.

Although the existing current good manufacturing practices (CGMP) regulations require separation of manufacturing facilities to avoid cross-contamination, the only class of products for which the regulations specify particular separation requirements are penicillins. This guidance explains that, due to the potential health risks of cross-contamination, the Agency expects separation for all classes of beta-lactam drugs, including penicillins as well as non-penicillin beta-lactams. Specifically, FDA recommends that manufacturers establish appropriate separation and control systems designed to prevent two types of contamination: (1) The contamination of a non-penicillin beta-lactam by any other non-penicillin beta-lactam and (2) the contamination of any other type of product by a non-penicillin beta-lactam. Accordingly, FDA recommends that the area in which any class of sensitizing beta-lactam is manufactured should be separated from areas in which any other products are manufactured, and should have an independent air handling system.

A draft version of this guidance was published in March 2011 as “Non-Penicillin Beta-Lactam Risk Assessment: A CGMP Framework.” This final version was revised in response to docket comments to clarify that this guidance does not provide a formal risk assessment, but, rather, describes FDA’s expectations and recommendations for separation strategies to prevent cross-contamination.

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 Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination. 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 either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

III. 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: April 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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