DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Draft Compliance Policy Guide

Crotalaria spp. Seeds in Grains: Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft Compliance Policy Guide (CPG) entitled “Compliance Policy Guide Sec. 100.101 Crotalaria spp. Seeds in Grain.” We previously provided guidance on *Crotalaria spectabilis* and *Crotalaria striata* seeds in grains in a CPG entitled “Compliance Policy Guide 7126.15 Crotalaria Seeds in Grains and Feeds” (CPG 7126.15), which we issued on December 1, 1980. We revoked CPG 7126.15 on July 22, 1994, because at the time we deemed the CPG to be no longer relevant (59 FR 37498). However, because *Crotalaria* plants persist in the agricultural environment and still present a potential public health risk, we continue to monitor grains for the presence of *Crotalaria* spp. seeds.

The draft CPG, when finalized, will represent our current thinking on *Crotalaria* spp. seeds in grains. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate 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 the draft CPG. 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 may be posted to the docket at http://www.regulations.gov.

III. Electronic Access


Dated: September 15, 2015.

Leslie Kux,
Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidelines for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-