DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2994]

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 Grains'' (the draft CPG). The draft CPG, when finalized, will provide guidance for FDA staff on our regulatory action guidance criteria for *Crotalaria* species (spp.) seeds in grains.

DATES: Although you can comment on any CPG at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft CPG before we begin work on the final version of the CPG, submit written or electronic comments on the draft CPG by November 20, 2015.

ADDRESSES: Submit electronic comments on the draft CPG to *http://www.regulations.gov*. Submit written comments on the draft CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft CPG to the Office of Policy and Risk Management, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

FOR FURTHER INFORMATION CONTACT: George C. Ziobro, Center for Food Safety and Applied Nutrition (HFS–316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1700; or Amber M. McCoig, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240–402–5556.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft 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.

We are making available the draft CPG because the revocation of CPG 7126.15 in 1994 inadvertently affected interactions between FDA and the U.S. Department of Agriculture's (USDA's) Federal Grain Inspection Service (FGIS). Under a Memorandum of Understanding between FDA and USDA (MOU 225–80–2000; *http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116312.htm*), FGIS reports to FDA's district offices the results of FGIS's analysis that may be actionable under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). FGIS has been using the CPG 7126.15 criteria for reporting their analytical results relating to *Crotalaria* in grain to FDA.

CPG 7126.25 established a regulatory action criterion of ''an average of at least one whole seed of *Crotalaria spectabilis* and/or *Crotalaria striata* per pound'' of grain. In developing the draft CPG, we converted the unit of weight from pounds to kilograms because metric units of measurement (*e.g.,* kilograms) are generally used for scientific calculations. The conversion from ''seeds per pound'' to ''seeds per kilogram'' resulted in 2.2 seeds per kilogram. Because the analytical method is based on determining whole seeds, we rounded 2.2 to the nearest number of whole seeds (*i.e.,* 2 whole seeds). The draft CPG also refers to *Crotalaria* spp. seeds in grain instead of *Crotalaria spectabilis* and *Crotalaria striata* because it is impracticable to distinguish between *Crotalaria* seeds based on species. Thus, the draft CPG states that FDA may regard grain that contains more than two whole *Crotalaria* spp. seeds per one kilogram of grain to be adulterated within the meaning of section 402(a)(1) of the FD&C Act (21 U.S.C. 342(a)(1)).

The draft CPG is being made available consistent with FDA's good guidance practices regulation (21 CFR 10.115). 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

Persons with access to the Internet may obtain the draft CPG from FDA's Office of Regulatory Affairs Compliance Policy Guide Revision/Update History page. It may be accessed at *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm* or *http://www.regulations.gov*. Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: September 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances 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-