Compliance Policy Guide Sec. 100.101 *Crotalaria* spp. Seeds in Grains: Guidance for FDA Staff

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments 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. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700 or the Center for Veterinary Medicine (CVM) at 240-276-9200.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Regulatory Affairs

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction:

The purpose of this document is to provide guidance for FDA staff on *Crotalaria* species (spp.) seeds in grains.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background:

Crotalaria spp. plants present a public health threat for humans and animals due to the presence of toxigenic pyrrolizidine alkaloids in the seeds. Some species of *Crotalaria* are used as a cover crop to improve soil properties, reduce soil erosion, conserve soil water, and recycle plant nutrients. However, if not properly managed, *Crotalaria* spp. seeds can germinate and invade or displace desirable plants in pastures and in fields of grain crops. When *Crotalaria* spp. plants are present in fields of grain crops, the *Crotalaria* spp. seeds may become comingled with the desired grain as the crop is harvested and processed. The introduction and growth of *Crotalaria* spp. in crop fields can be controlled by good agricultural practices to reduce or eliminate unwanted plants.

III. Policy:

FDA may regard grain that contains more than two (2) whole *Crotalaria* seeds per one (1) kilogram of grain to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(1)). Under

section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)), FDA may refuse admission of grain that is offered for import and appears to be adulterated within the meaning of section 402(a)(1).

IV. Regulatory Action Guidance:

The following represents criteria for recommending seizure or import refusal of grain that may be intended for human food to the Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Enforcement (HFS-605) and for recommending seizure or import refusal of grain that may be intended for food for animals to the Center for Veterinary Medicine, Division of Compliance (HFV-230):

> The grain contains more than two (2) whole *Crotalaria* spp. seeds per one (1) kilogram of grain.

Refer to Investigations Operations Manual Sample Schedule 4: Wheat Carload Sampling for instructions on sampling grain in railcars, barges, trucks, and other large containers or storage vessels.

The United States Department of Agriculture's Federal Grain Inspection Service (FGIS) reports to the FDA district offices the results of their analysis of grain that contains more than two (2) whole *Crotalaria* spp. seeds per one (1) kilogram of grain. FDA district offices should follow-up as necessary with FGIS regarding the disposition of lots of grain sampled by FGIS that are found to meet the actionable level. (See Memorandum of Understanding (MOU 225-80-2000) between FGIS and FDA).

V. Specimen Charges:

Domestic Seizure

The article of food was adulterated when introduced into interstate commerce or while in interstate commerce or while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(a)(1), in that it bears or contains an added poisonous or deleterious substance, namely *Crotalaria* spp. seeds, which may render it injurious to health.

Import Refusal

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act, in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it bears or contains an added poisonous or deleterious substance, namely *Crotalaria* spp. seeds, which may render it injurious to health.

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