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.

[FR Doc. 2015–23619 Filed 9–18–15; 8:45 am]

BILLING CODE 4164–01–P

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-

specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

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 comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by November 20, 2015.

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, 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 draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations 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: Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** on June 30, 2015 (80 FR 37273). This notice announces draft product-specific recommendations, either new or revised, that are posted on FDA's Web site.

II. Drug Products for Which New Draft Product-Specific BE Recommendations are Available

FDA is announcing the availability of a new draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

Aclidinium bromide
Acyclovir
Aminocaproic acid
Apremilast
Benazepril hydrochloride; Hydrochlorothiazide
Brimonidine tartrate
Carbidopa; Levodopa
Ceritinib
Clobetasol propionate
Clomipramine hydrochloride
Clonidine hydrochloride
Cobicistat
Cysteamine bitartrate
Dapagliflozin propanediol; Metformin hydrochloride
Dasabuvir sodium; Ombitasvir; Paritaprevir; Ritonavir
Desvenlafaxine fumarate
Eslicarbazepine acetate
Esomeprazole magnesium
Ferric citrate
Fluticasone propionate (multiple reference listed drugs)
Formoterol fumarate
Idelalisib
Ledipasvir; Sofosbuvir
Levocarnitine
Loperamide hydrochloride; Simethicone
Mometasone furoate monohydrate
Naltrexone HCL; Bupropion HCL
Netupitant; Palonosetron hydrochloride
Nintedanib esylate
Nortriptyline hydrochloride
Pirfenidone
Pomalidomide
Ponatinib hydrochloride
Rivaroxaban
Ruxolitinib phosphate
Suvorexant
Tasimelteon
Tedizolid phosphate
Tramadol hydrochloride
Trimipramine maleate

III. Drug Products for Which Revised Draft Product-Specific BE Recommendations are Available

FDA is announcing the availability of a revised draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

Acitretin
Amantadine hydrochloride
Benzonatate
Carbamazepine
Colesevelam hydrochloride
Cyclophosphamide
Dabigatran etexilate mesylate
Dasatinib
Desvenlafaxine succinate
Esomeprazole magnesium
Estradiol
Ethinyl estradiol; Norethindrone
Gabapentin
Isotretinoin
Minocycline hydrochloride
Naltrexone
Sevelamer carbonate
Sirolimus

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, go to *http://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft and revised draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represent the Agency's current thinking on product-specific design of BE studies to support ANDAs. They do not establish any rights for anyone and are not binding on FDA or the public. You may use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Comments

Interested persons may submit either electronic comments on any of the specific BE recommendations posted on FDA's Web site 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. The guidances, notices, and 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.*

V. 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: September 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–23571 Filed 9–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0025]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Animal Food Labeling; Declaration of Certifiable Color Additives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Animal Food Labeling; Declaration of Certifiable Color Additives'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On July 16, 2015, the Agency submitted a proposed collection of information entitled ''Animal Food Labeling; Declaration of Certifiable Color Additives'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0721. The approval expires on August 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: September 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–23566 Filed 9–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3224]

Request for Nominations of Individuals and Consumer Organizations for the Patient Engagement Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of a voting consumer representative to serve on the Patient Engagement Advisory Committee (the Committee) notify FDA in writing. FDA is also requesting nominations for a voting consumer representative to serve on the Committee. Nominees recommended to serve as a voting consumer representative may either be self-nominated or may be nominated by a consumer organization. Nominations will be accepted for the current vacancy effective with this notice.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting member to represent consumer interests on the Committee may send a letter or email stating that interest to FDA by October 21, 2015. Concurrently, nomination materials for prospective candidates should be sent to FDA by October 21, 2015.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process should be sent electronically to Kimberly Hamilton (see **FOR FURTHER INFORMATION CONTACT**). All Consumer Representative nominations may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm,* by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, or FAX: 301–847–8640. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: *For questions relating to participation in the selection process:* Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5117, Silver Spring, MD 20993–0002, 301–796–6319, *kimberly.hamilton@fda.hhs.gov.*

For questions relating to the Committee: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002, 301–796–8398, *letise.williams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for a voting consumer representative on the Committee.

Elsewhere in this issue of the **Federal Register**, FDA is publishing separate documents regarding:

1. Patient Engagement Advisory Committee; Notice of Establishment.
2. Request for Nominations for Voting Members for the Patient Engagement Advisory Committee.
3. Request for Nominations of Individuals and Industry Organizations for the Patient Engagement Advisory Committee.

I. General Description of the Committee's Duties

The Committee provides advice on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues are among the topics that may be considered by the Committee. Members are knowledgeable in areas such as clinical research, primary care patient experience, health care needs of patient groups in the