ComplianceRegulatoryInformation/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 September 21, 2015 (80 FR 57000). 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 new draft guidances 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

Alprostadil.
Atazanavir sulfate; cobicistat.
Beclomethasone dipropionate.
Betamethasone dipropionate.
Betamethasone valerate.
Betaxolol hydrochloride.
Ciclesonide.
Clobetasol propionate.
Desonide (multiple reference listed drugs).
Diflorasone diacetate (multiple reference listed drugs).
Difluprednate emulsion.
Elvitegravir.
Erythromycin.
Ethinyl estradiol; norethindrone acetate.
Flurandrenolide.
Formoterol fumarate; mometasone furoate.
Ingenol mebutate (multiple strengths).
Mercaptopurine.
Methylphenidate hydrocholoride.
Metronidazole.
Mometasone furoate.
Naftifine hydrochloride (multiple reference listed drugs).
Nicotine.
Olanzapine pamoate.
Omega-3-carboxylic acids.
Prednisone.
Ranitidine hydrochloride.
Riociguat.
Spinosad.
Trametinib dimethyl sulfoxide.
Vorapaxar sulfate.

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FDA is announcing the availability of a revised draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients: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

Abiraterone acetate.
Amphotericin B.
Ciprofloxacin hydrochloride; hydrocortisone.
Colesevelam hydrochloride.
Drospirenone; estradiol.
Guanfacine hydrochloride.
Lidocaine.
Lomitapide mesylate.
Methylphenidate hydrochloride.
Phytonadione.
Rivastigmine tartrate.

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

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: January 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01682 Filed 1–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0438]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' 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 October 8, 2015, the Agency submitted a proposed collection of information entitled ''Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' 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 0910–0583. The approval expires on November 30, 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: January 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01686 Filed 1–27–16; 8:45 am]

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