Dated: July 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17294 Filed 7–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1496]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Generic Food and Drug Administration Rapid Response Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Generic FDA Rapid Response Surveys'' 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 April 23, 2014, the Agency submitted a proposed collection of information entitled ''Generic FDA Rapid Response Surveys'' 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 0910–0500. The approval expires on July 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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,'' which 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 September 22, 2014.

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, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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: Kris André, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1615, Silver Spring, MD 20993–0002, 240–402–7959.

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'' which 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/GuidanceComplianceRegulatoryInformation/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 April 2, 2014 (79 FR 18561). 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

A	Alogliptin benzoate.
	Alogliptin benzoate; Metformin hydrochloride (HCl).
	Alogliptin benzoate; Pioglitazone HCl.
	Amoxicillin (multiple reference listed drugs).
	Atenolol; Chlorthalidone.
C	Canagliflozin.
	Carbidopa.
	Carbinoxamine maleate.

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

	Cefixime.
	Colestipol HCl.
	Crizotinib.
D	Daunorubicin citrate.
	Diflorasone diacetate.
	Dimethyl fumarate.
	Diphenhydramine HCl.
	Doxycycline (multiple reference listed drugs).
	Doxylamine succinate; Pyridoxine HCl.
E	Esomeprazole strontium.
	Ethinyl estradiol; Levonorgestrel and Ethinyl estradiol.
	Ethinyl estradiol; Norethindrone acetate.
F	Fosfomycin tromethamine.
G	Gentamicin sulfate.
H	Hydromorphone HCl.
L	Lanreotide acetate.
	Linagliptin; Metformin HCl.
	Lomustine.
M	Menthol; Methyl salicylate.
	Metformin HCl; Sitagliptin phosphate.
O	Ospemifene.
	Oxcarbazepine.
P	Paroxetine mesylate.
	Promethazine (multiple reference listed drugs and strengths).
	Propranolol HCl.
R	Ropinirole HCl.
S	Sucralfate (multiple reference listed drugs and dosage forms).
T	Tacrolimus.
Z	Zolmitriptan.

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

D	Dronedarone HCl.
	Duloxetine HCl.
E	Ergocalciferol
	Esomeprazole magnesium.
F	Fluorouracil.
H	Hydrochlorothiazide; Moexipril HCl.
I	Imatinib mesylate.
L	Lansoprazole.
M	Mesalamine (multiple reference listed drugs).
N	Nevirapine.
	Nilotinib HCl monohydrate.
P	Pentosan polysulfate sodium.

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, please 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 create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach 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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.*

Dated: *July 17, 2014.*

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: HHS is announcing the availability of an interpretive rule providing HHS's interpretation of section 340B(e) of the Public Health Service Act (PHSA), entitled ''Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program.'' The interpretive rule states that section 340B(e) of the PHSA excludes drugs with an orphan designation only when those drugs are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the drug was designated under section 526 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Effective July 23, 2014.

ADDRESSES: Submit written requests for single copies of the interpretive rule to the Office of Pharmacy Affairs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8W03A, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the interpretive rule.

FOR FURTHER INFORMATION CONTACT: CDR Krista Pedley, Director, Office of Pharmacy Affairs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8W03A, Rockville, MD 20857, or by telephone at (301) 594–4353.

SUPPLEMENTARY INFORMATION:

I. Background

HHS is announcing the availability of an interpretive rule entitled ''Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program.'' This interpretive rule explains how HHS interprets section 340B(e) of the PHSA. 42 U.S.C. 256b(e). This interpretive rule intends to: (1) Provide clarity in the marketplace; (2) maintain the 340B Program savings for newly-eligible entities; and (3) protect the financial incentives for manufacturing orphan drugs designated for a rare disease or condition, as indicated in the Patient Protection and Affordable Care Act (''Affordable Care Act'') (Pub. L. 111–148) and intended by Congress.

Earlier this year, after notice and comment rulemaking, HHS issued a final rule on this subject, ''Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program'' (78 FR 44016, July 23, 2013) (the ''Rule''). The Rule was vacated by U.S. District Court for the District of Columbia on May 23, 2014, on the grounds that HHS does not have the authority to issue the Rule as a substantive rule. *PhRMA* v. *HHS,* No. 13–01501 (D.D.C. May 23, 2014). However, the decision did not invalidate HHS's interpretation of the orphan drug exclusion in the Rule.