TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Type of respondent	Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
	Second follow up young adult outcome evaluation questionnaire.	788	1	788	0.667 (40 min.)	526
	Third follow up young adult outcome evaluation questionnaire.	788	1	788	0.667 (40 min.)	526
LGBT young adults aged 18–24 in the select media markets—Recruited via social media.	1st media tracking screener.	1667	1	1667	0.083 (5 min.)	138
	1st media tracking questionnaire.	500	1	500	0.667 (40 min.)	334
	2nd media tracking screener.	1667	1	1667	0.083 (5 min.)	138
	2nd media tracking questionnaire.	500	1	500	0.667 (40 min.)	334
	3rd media tracking screener.	1667	1	1667	0.083 (5 min.)	138
	3rd media tracking questionnaire.	500	1	500	0.667 (40 min.)	334
Total	.....	37,477	.....	.....	.....	10,819

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16020 Filed 6–29–15; 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 August 31, 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/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 March 9, 2015 (80 FR 12502). 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

Abacavir sulfate; Dolutegravir sodium; Lamivudine.
Afatinib dimaleate.
Alendronate sodium.
Aspirin.
Azelastine hydrochloride; Fluticasone propionate.
Budesonide; Formoterol fumarate dihydrate.
Calcium carbonate; Famotidine; Magnesium hydroxide.
Canagliflozin; Metformin hydrochloride.
Cyclophosphamide.
Cyproheptadine hydrochloride.
Dabrafenib mesylate.
Dapagliflozin propanediol.
Dexbrompheniramine maleate and Pseudoephedrine sulfate.
Dolutegravir sodium.
Donepezil hydrochloride; Memantine hydrochloride.
Doxycycline hyclate.
Droxidopa.
Eliglustat tartrate.
Empagliflozin.
Emtricitabine; Tenofovir disoproxil fumarate.
Enzalutamide.
Fentanyl.
Indomethacin.
Lanthanum carbonate.
Levalbuterol tartrate.
Levomilnacipran hydrochloride.
Macitentan.
Methazolamide.
Miglitol.
Naloxegol oxalate.
Naproxen sodium.
Nitroglycerin.
Omeprazole; Sodium bicarbonate.
Oxybutynin (multiple reference listed drugs and dosage forms).
Oxycodone hydrochloride.
Primaquine phosphate.
Sildenafil citrate.
Simeprevir sodium.
Sofosbuvir.
Tolcapone.
Vemurafenib.
Vismodegib.
Vortioxetine hydrobromide.

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 CHOLESTYRAMINE

Doxycycline hyclate.

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

Prasugrel hydrochloride.
Tiagabine hydrochloride.

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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16013 Filed 6–29–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2261]

Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings.'' FDA is issuing this draft guidance to describe the Agency's premarket regulatory requirements and the performance testing needed to support liquid barrier claims for gowns intended for use in health care settings. This draft guidance is being issued in light of the public health importance of personal protective equipment in health care settings and the recognition that terminology used to describe gowns has evolved, including by industry, the standards community, and health care professionals. This draft guidance is not final nor is it in effect at this time.

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 comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 31, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Claverie, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2508, Silver Spring, MD 20993–0002, 301–796–6298.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued a final rule on June 24, 1988 (53 FR 23874), defining ''surgical apparel'' under 21 CFR 878.4040. Under this 1988 final rule, surgical gowns and surgical masks were classified as Class II subject to premarket review under section 510(k) (21 U.S.C. 351) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), and surgical apparel other than surgical gowns and surgical masks were classified as Class I also subject to 510(k) premarket review requirements. On January 14, 2000, FDA issued a final rule (65 FR 2318) to designate as exempt from premarket notification requirements surgical apparel other than surgical gowns and surgical masks, subject to the limitations of exemptions under 21 CFR 878.9, which includes requiring a premarket notification for devices intended for a use different from the intended use of a legally marketed device in that generic type of device.

Since the original 1988 final rule, a number of terms have been used to refer to gowns intended for use in health care settings including, but not limited to, surgical gowns, isolation gowns, surgical isolation gowns, nonsurgical gowns, procedural gowns, and operating room gowns. In 2004, FDA recognized the consensus standard American National Standards Institute/Association of the Advancement of Medical Instrumentation (ANSI/AAMI) PB70:2003, ''Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.'' ANSI/AAMI PB 70 utilized new terminology for barrier performance of gowns. This terminology described and assessed the barrier protection levels of gowns and other protective apparel intended for use in health care facilities, by specifying test methods and performance results necessary to verify and validate the newly defined levels of barrier protection. The definitions and terminology used in this standard are inconsistent with FDA's historical definitions of these terms and thus have added confusion in the marketplace. The purpose of this draft guidance is to clarify and describe the premarket regulatory requirements pertaining to gowns regulated under § 878.4040 and the performance testing needed to support liquid barrier claims for gowns intended for use in health care settings.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's current thinking on performance testing to support liquid barrier claims for gowns intended for use in health care settings. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Premarket Notification