Amendments Act of 2007 (Public Law 110–85), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications, biologics license applications, or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. Form FDA 3397, the user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2008, there are an estimated 255 manufacturers of products subject to the user fee provisions of PDUFA. However, not all manufacturers will have any submissions, and some may have multiple submissions in a given year. The total number of annual responses is based on the number of submissions received by FDA in FY 2008. CDER received 3,107 annual responses that include the following submissions: 147 new drug applications; 13 biologics license applications; 1,813 manufacturing supplements; 987 labeling supplements; and 147 efficacy supplements. CBER received 810 annual responses that include the following submissions: 9 biologics license applications; 743 manufacturing supplements; 48 labeling supplements; and 10 efficacy supplements. Based on the previous submissions that were received, the rate of these submissions is not expected to change significantly in the next few years. The estimated hours per response are based on past FDA experience with the various submissions, and the average is 30 minutes.

FDA is revising Form FDA 3397 in the following ways: (1) By including an additional question regarding redemption of a priority review voucher; (2) by deleting the exclusion for certain applications submitted under section 505(b)(2) of the FD&C Act (21 U.S.C. 355(b)(2)); and (3) by making several minor editorial changes.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3397	255	15.36	3,917	0.5	1,959

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

Dated: June 1, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–13276 Filed 6–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369] (formerly Docket No. 2007D–0169)

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 May 31, 2007, FDA announced the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' explaining 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. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of final product-specific BE recommendations.

DATES: Submit written or electronic comments on the draft and revised draft product-specific BE recommendations listed in this notice by September 8, 2009.

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. Submit written comments on the draft product-specific BE recommendations to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the recommendations.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9314.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft 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/cder/guidance/bioequivalence/default.htm*. As described in that draft 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 90 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** of September 5, 2008 (73 FR 51829). This notice announces draft product-specific recommendations, either new or revised, that have been posted on FDA's Web site in the period from May 1, 2008, through October 31, 2008. Final product-specific recommendations are being announced elsewhere in this issue of the **Federal Register**.

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

FDA is announcing draft BE product-specific recommendations for drug products containing the following active ingredients:

A
Acetazolamide
Adefovir Dipivoxil
Albuterol Sulfate
Aliskiren Hemifumarate
Alprazolam
Aminosalicylic Acid
Amlodipine Besylate; Olmesartan Medoxomil

Amlodipine Besylate; Valsartan
Amprenavir
Atovaquone; Proguanil
Azacitidine
Azithromycin

B
Baclofen
Bethanechol Chloride
Bismuth Subcitrate Potassium; Metronidazole; Tetracycline HCl
Brimonidine Tartrate
Bumetanide
Busulfan

C
Calcitriol
Capecitabine
Citalopram HBr (multiple dosage forms)
Clotrimazole
Colesevelam HCl
Cyclobenzaprine HCl

D
Demeclocycline HCl
Desogestrel; Ethinyl Estradiol
Diflunisal
Disopyramide Phosphate (multiple dosage forms)
Doxercalciferol
Doxycycline
Doxycycline Hyclate

E
Efavirenz; Emtricitabine; Tenofovir Disoproxil Fumarate
Enalapril Maleate
Eprosartan Mesylate
Escitalopram Oxalate
Ethinyl Estradiol; Levonorgestrel
Ethinyl Estradiol; Norethindrone Acetate (multiple reference listed drugs (RLDs))
Ethosuximide
Ezetimibe; Simvastatin
Ezetimibe

F
Famciclovir
Fenofibrate (multiple dosage forms)
Fexofenadine HCl
Frovatriptan Succinate

G
Gatifloxacin
Glipizide
Goserelin Acetate
Griseofulvin, Ultramicrocrystalline

H
Hydrochlorothiazide; Telmisartan
Hydrochlorothiazide; Triamterene
Hydralazine HCl
Hydroxyurea

I
Ibuprofen (multiple dosage forms)
Indapamide
Isoniazid
Isotretinoin

K
Ketoconazole
Ketorolac Tromethamine

L
Lansoprazole
Latanoprost
Letrozole
Leucovorin Calcium
Leuprolide Acetate
Levocetirizine Dihydrochloride
Levofloxacin
Lisdexamfetamine Dimesylate
Lithium Carbonate
Lopinavir; Ritonavir
Loratadine

M
Mebendazole
Melphalan
Metformin HCl
Methadone HCl
Midodrine HCl
Minocycline HCl
Montelukast
Montelukast Sodium
Moxifloxacin HCl

N
Nabilone
Naltrexone HCl
Naproxen Sodium (multiple RLDs)
Naratriptan HCl
Nicardipine HCl

O
Olanzapine
Olopatadine HCl
Omeprazole; Sodium Bicarbonate

P
Paroxetine HCl
Penicillamine
Phenoxybenzamine HCl
Prednisolone Sodium Phosphate

Q
Quetiapine Fumarate

R
Ramipril
Repaglinide

S
Sapropterin Dihydrochloride
Selegiline HCl
Sevelamer Carbonate
Sevelamer HCl
Simvastatin
Sitagliptin Phosphate; Metformin HCl
Sodium Iodide
Stavudine
Sulfadiazine
Sulfamethoxazole; Trimethoprim

T
Theophylline
Tiagabine HCl
Triptorelin Pamoate
Trospium Cl

U
Ursodiol

V
Valganciclovir HCl
Verapamil HCl
Vorinostat

Z
Zileuton
Ziprasidone HCl

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

FDA is announcing revised draft BE product-specific recommendations for drug products containing the following active ingredients. These recommendations were previously posted on FDA's Web site.

A
Alprazolam

C
Candesartan Cilexetil; Hydrochlorothiazide

Carbidopa; Entacapone; Levodopa
Clopidogrel Bisulfate

F
Fexofenadine HCl (multiple dosage forms)

Fosinopril Sodium; Hydrochlorothiazide

H

Hydrochlorothiazide; Valsartan

M

Minoxidil

Montelukast Sodium

Morphine Sulfate

S

Sirolimus

Z

Zolmitriptan

For a complete history of previously published Federal Register notices, please go to *http://www.regulations.gov* and enter docket number FDA–2007–D–0369.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The 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 to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on any of the specific BE recommendations posted on FDA's Web site. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance, notices, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: May 27, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–13272 Filed 6–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369] (formerly Docket No. 2007D–0169)

Final 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 final 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 May 31, 2007, FDA announced the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' explaining 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. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of additional draft and revised draft product-specific BE recommendations.

DATES: Submit written or electronic comments on agency guidances at any time.

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. Submit written comments on the product-specific BE recommendations to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the recommendations.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9314.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft 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/cder/guidance/bioequivalence/default.htm*. As described in that draft 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 90 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. Once finalized, the recommendations are posted on FDA's Web site and announced in the **Federal Register**. This notice announces product-specific recommendations that have been posted on FDA's Web site from May 1, 2008, through October 31, 2008. Additional draft and revised draft product-specific BE recommendations are being announced elsewhere in this issue of the **Federal Register**.

II. Drug Products for Which Final Product-Specific BE Recommendations Are Available

FDA is announcing final BE product-specific recommendations for drug products containing the following active ingredients:

A

Abacavir Sulfate

Abacavir Sulfate; Lamivudine; Zidovudine

Acamprosate Calcium

Acyclovir

Almotriptan Malate

Alosetron HCl

Amlodipine Besylate

Amlodipine Besylate; Benazepril HCl

Amoxicillin; Clavulanate Potassium

Anagrelide HCl

Anastrozole

Aprepitant