Any application by Mr. Izurieta for termination of debarment under section 306(d)(1) (21 U.S.C. 335a(d)(1)) of the FD&C Act should be identified with Docket No. FDA–2011–N–0592 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

DATED: January 11, 2012.

Armando Zamora,
Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2012–1489 Filed 1–24–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369; (Formerly Docket No. 2007D–0168)]

Draft and Revised Draft Guidelines 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 In the Federal Register of May 31, 2007, FDA announced the availability of a draft guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site. In the Federal Register of May 31, 2007 (72 FR 30386), FDA announced the availability of a draft guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” explaining the process that would be used to make product-specific BE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.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(6)), to ensure that the Agency considers your comments on these draft and revised draft guidelines before it begins work on the final versions of the guidelines, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by March 26, 2012.

ADDRESSES: Submit written requests for single copies of the individual BE guidelines to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

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) 276–8608.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of May 31, 2007, FDA announced the availability of a draft 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/GuidanceCompliance/ RegulatoryInformation/Guidances/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 the 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 of December 1, 2009 (74 FR 62793). This notice announces draft product-specific recommendations, either new or revised, that have been posted on the FDA’s Web site in the period from December 1, 2009, through June 30, 2011.

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

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

A

Acetaminophen

Acetaminophen; Butalbital (multiple reference listed drugs (RLDs))

Acetazolamide

Adapalene

Aliskiren Hemifumarate; Valsartan

Altretamine

Amitriptyline HCl

Amitriptyline HCl (multiple RLDs)

Amlodipine Besylate; Telmisartan

Amlodipine; Hydrochlorothiazide; Valsartan

Amoxicillin; Clavulanate Potassium (multiple RLDs)

Aripiprazole

Aspirin; Butalbital; Caffeine (multiple RLDs)

Aspirin; Dipyridamole

Aspirin; Oxycodeone

Aspirin; Butalbital; Caffeine; Codeine Phosphate

Atenolol

Auranofin

Azelaic Acid (multiple RLDs)

B

Baclofen (multiple RLDs)

Benazepril HCl

Benzoil Peroxide Clindamycin Phosphate (multiple RLDs)

Benzoyl Peroxide; Erythromycin (multiple RLDs)

Betamethasone Acetate; Sodium Phosphate

Betamethasone Dipropionate; Calcipotriene Hydrate (multiple RLDs)

Betamethasone Dipropionate; Clotrimazole

Betamethasone; Clotrimazole

Bexarotene

Bosentan

Buprenorphine HCl

Buprenorphine HCl; Naloxone HCl

Bupropion HBr

Bupropion HCl

Buspirone

Butacnazol Nitrato (multiple RLDs)

C

Calcipotriene (multiple RLDs)

Carbidopa; Levodopa

Carisoprodol

Carvedilol Phosphate

Cefadroxil

Cefadroxil; Cefadroxil Hemihydrate

Cefditoren Pivoxil

Cefixime

Cefoxime Axitil (multiple RLDs)

Cetirizine HCl

Chlorambucil

Chlorpheniramine Polistirex; Hydrocodone Polistirex
II. 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 the FDA’s Web site:

A
Amantadine HCl
Atorvastatin
B
Bupropion HBr
C
Calcipotriene
Calcium Acetate
Calcitriol
Capcicitabine (multiple RLDs)
Celzidorin Pivoxil
Ciclopirox
Clofibrate
Colestipol HCl
Colestipol

D
Darunavir Ethanolate
Desogestrel; Ethinyl Estradiol
Desvenlafaxine Succinate
Diclofenac Sodium
Diclofenac Sodium; Misoprostol
Disulfiram
Donepezil HCl (multiple RLDs)

E
Emtricitabine
Esomeprazole Magnesium
Estradiol
Ethinyl Estradiol; Ethynodiol Diacetate
Ethynodiol Diacetate (multiple RLDs)
Ethynol Estradiol; Norethindrone

F
Felbamate (multiple RLDs)
Fentanyl
Fentanyl Citrate
Fluorouracil (multiple RLDs)

G
Glyburide Metformin
Granisetron HCl

L
Labetalol HCl
Lamotrigine (multiple RLDs)
Lapatinib Ditosylate
Levofoxcin
Levonorgestrel (multiple RLDs)
Limenolid
Minocycline
Minocycline (multiple RLDs)

M
Memantine HCl
Mercaptopurine (multiple RLDs)
Mephenytoin HCl (multiple RLDs)
Mexitidil
Methadone HCl

N
Nevirapine
Niacin

O
Omeprazole
Oxaliplatin (multiple RLDs)
Oxymorphone HCl

P
Prednisolone
Progesterone

R
Rabepredo HCl
Rabepredo
Ragozine
Ranitidine
Ranolazine
Rilastatin
Rivastigmine
Rivastigmine Tartrate
Ropinore

S
Scopolamine
Sevelamer Carbonate (multiple RLDs)
Sevelamer HCl (multiple RLDs)
Sirolimus

T
Telmisartan
Tiagabine HCl
Tramexame Acid
Triamcinolone Acetonide (multiple RLDs)

V
Varenicline Tartrate
Venlaxafine HCl


These draft and revised draft guidelines are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidelines 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) either electronic or written comments on any of the specific BE recommendations posted on FDA’s Web site. 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 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/Drugs/
GuidanceCompliance
RegulatoryInformation/Guidances/