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]

BILLING CODE 4160–01–P

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 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 In the **Federal Register** of May 31, 2007 (72 FR 30386), FDA announced the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' explaining the process that would be used to make product-specific BE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)(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 March 26, 2012.

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:

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/GuidanceComplianceRegulatoryInformation/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))
Acetaminophen; Butalbital; Caffeine (multiple RLDs)
Acetaminophen; Hydrocodone Bitartrate (multiple RLDs)
Acetaminophen Oxycodone (multiple RLDs)
Acetazolamide
Adapalene
Aliskiren Hemifumarate; Valsartan
Altretamine
Amantadine HCl (multiple RLDs)
Amiodarone 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; Oxycodone
Aspirin; Butalbital; Caffeine; Codeine Phosphate
Atovaquone
Auranofin
Azelaic Acid (multiple RLDs)

B

Baclofen (multiple RLDs)
Benazepril HCl
Benzoyl 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
Butoconazole Nitrate (multiple RLDs)

C

Calcipotriene (multiple RLDs)
Carbidopa; Levodopa
Carisoprodol
Carvedilol Phosphate
Cefaclor
Cefadroxil; Cefadroxil Hemihydrate
Cefditoren Pivoxil
Cefixime
Cefuroxime Axetil (multiple RLDs)
Cetirizine HCl
Chlorambucil
Chlorpheniramine Polistirex; Hydrocodone Polistirex

Chlorthalidone (multiple RLDs)
Choline Fenofibrate (multiple RLDs)
Ciclopirox (multiple RLDs)
Ciprofloxacin HCl (multiple RLDs)
Clarithromycin
Clindamycin Phosphate (multiple RLDs)
Clobetasol Propionate (multiple RLDs)
Clonazepam
Clonidine
Clotrimazole (multiple RLDs)
Clozapine
Colchicine
Colesevelam HCl
Cyclobenzaprine

D

Dapsone (multiple RLDs)
Darunavir Ethanolate
Dexamethasone
Dexamethasone; Tobramycin
Dexlansoprazole
Diazepam
Diclofenac Potassium
Diclofenac Sodium (multiple RLDs)
Dienogest; Estradiol Valerate
Diethylpropion
Diphenhydramine; Ibuprofen
Disulfiram (multiple RLDs)
Divalproex Sodium
Dolasetron Mesylate
Donepezil HCl
Doxazosin Mesylate
Doxepin HCl (multiple RLDs)
Doxorubicin HCl
Dronabinol
Dronedarone HCl

E

Econazole Nitrate
Ergocalciferol
Erythromycin (multiple RLDs)
Erythromycin Ethylsuccinate; Sulfisoxazole Acetyl
Esomeprazole Magnesium
Esomeprazole Magnesium; Naproxen
Estradiol (multiple RLDs)
Estrogens Conjugated Synthetic A
Ethacrynic Acid
Ethinyl Estradiol; Norethindrone
Ethinyl Estradiol; Norethindrone Acetate
Ethinyl Estradiol; Norgestimate (multiple RLDs)
Etodolac
Etoposide
Everolimus

F

Febuxostat
Felodipine
Fenofibrate
Fenofibric Acid
Fentanyl Citrate
Fesoterodine Fumarate
Finasteride
Flucytosine
Fluorouracil (multiple RLDs)
Fluoxetine HCl (multiple RLDs)
Fluticasone Propionate
Fluvoxamine Maleate
Furosemide

G

Galantamine HBr
Gemfibrozil
Glipizide
Griseofulvin
Griseofulvin Microcrystalline
Guanfacine HCl

H

Hydrochlorothiazide; Moexipril
Hydrochlorothiazide; Spironolactone
Homatropine Methylbromide; Hydrocodone Bitartrate
Hydralazine; Isosorbide
Hydrochlorothiazide
Hydrochlorothiazide; Quinapril HCl
Hydrocodone; Ibuprofen (multiple RLDs)
Hydromorphone HCl
Hydroxychloroquine
Hydroxyzine HCl (multiple RLDs)

I

Ibuprofen (multiple RLDs)
Iloperidone
Imipramine Pamoate
Imiquimod (multiple RLDs)
Indomethacin (multiple RLDs)

K

Ketoconazole

L

Labetalol HCl
Lamotrigine
Lansoprazole
Lapatinib Ditosylate
Lenalidomide
Leuprolide Acetate (multiple RLDs)
Levetiracetam
Levonorgestrel
Lithium Carbonate (multiple RLDs)
Loratadine; Pseudoephedrine Sulfate
Lorazepam
Loteprednol
Lubiprostone

M

Maraviroc
Meclizine
Meclizine HCl
Mefenamic Acid
Megestrol Acetate (multiple RLDs)
Mestranol; Norethindrone
Metformin HCl; Pioglitazone HCl
Methimazole
Methoxsalen (multiple RLDs)
Methylphenidate
Methylphenidate HCl
Methylprednisolone
Metoclopramide HCl
Metolazone
Metoprolol Tartrate; Hydrochlorothiazide
Metronidazole (multiple RLDs)
Mifepristone
Milnacipran HCl
Minocycline HCl
Minoxidil (multiple RLDs)
Mirtazapine
Misoprostol
Molindone HCl
Morphine Sulfate (multiple RLDs)
Mupirocin
Mupirocin Calcium (multiple RLDs)
Mycophenolate Mofetil

N

Naltrexone HCl
Naproxen
Naproxen Sodium
Naproxen Sodium; Sumatriptan Succinate
Nebivolol
Niacin; Simvastatin
Nicotine Polacrilex
Nifedipine
Nilotinib HCl Monohydrate
Nitroglycerin (multiple RLDs)
Nystatin (multiple RLDs)

O

Octreotide
Ofloxacin
Orlistat (multiple RLDs)
Orphenadrine Citrate
Oseltamivir Phosphate (multiple RLDs)
Oxybutynin
Oxycodone
Oxycodone HCl (multiple RLDs)
Oxymetholone

P

Palonosetron HCl
Pantoprazole Sodium
Paroxetine
Penbutolol
Penicillin V Potassium
Perphenazine (multiple RLDs)
Phenelzine Sulfate
Phytonadione
Pioglitazone HCl
Pitavastatin
Potassium Citrate
Pramipexole Dihydrochloride
Prasugrel HCl
Prednisolone Acetate
Progesterone
Promethazine HCl (multiple RLDs)
Propafenone HCl
Propranolol HCl
Protriptyline HCl
Pseudoephedrine HCl

R

Rabeprazole Sodium
Ranitidine HCl
Ranolazine
Rifabutin
Risedronate
Risperidone (multiple RLDs)
Ritonavir
Rivastigmine
Ropinirole HCl

S

Sevelamer Carbonate
Sitagliptin Phosphate
Sotalol (multiple RLDs)
Spironolactone
Sulfacetamide Sodium
Sulfasalazine (multiple RLDs)
Sunitinib Malate

T

Tapentadol HCl
Tazarotene (multiple RLDs)
Terbinafine HCl
Terconazole (multiple RLDs)
Tetracycline
Theophylline (multiple RLDs)
Tioconazole
Tizanidine HCl
Topotecan
Tranexamic Acid
Trazodone HCl (multiple RLDs)
Tretinoin
Triamcinolone Acetonide (multiple RLDs)
Triazolam
Trimethoprim

U

Ursodiol

V

Valproic Acid
Venlafaxine HCl
Verapamil HCl

W

Warfarin Sodium

Z

Zolmitriptan
Zolpidem

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 the FDA's Web site:

A

Amantadine HCl
Atorvastatin

B

Bupropion HBr

C

Calcipotriene
Calcium Acetate
Calcitriol
Capecitabine (multiple RLDs)
Cefditoren Pivoxil
Ciclopirox
Clotrimazole
Colesevelam HCl (multiple RLDs)

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 (multiple RLDs)
Ethinyl 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
Levofloxacin
Levonorgestrel (multiple RLDs)
Linezolid

M

Memantine HCl
Mercaptopurine (multiple RLDs)
Metformin HCl (multiple RLDs)
Minoxidil
Morphine

N

Nebivolol
Niacin
Nilutamide
Nitroglycerin

O

Omeprazole
Orlistat (multiple RLDs)
Oxymorphone HCl

P

Prednisolone
Progesterone

R

Rivastigmine
Rivastigmine Tartrate
Ropinirole

S

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

T

Telmisartan
Tiagabine HCl
Topiramate
Tranexamic Acid
Triamcinolone Acetonide (multiple RLDs)

V

Varenicline Tartrate
Venlafaxine HCl

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 draft and revised draft 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**) 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/default.htm* or *http://www.regulations.gov.*

Dated: January 19, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–1433 Filed 1–24–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–4079 (Formerly Docket No. 1999D–0254)]

Guidance for Industry on Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling.'' The guidance is intended to clarify for applicants the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertising for prescription human and animal drugs and biological products. This guidance finalizes the draft guidance published in January 1999.

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

ADDRESSES: Submit written requests for single copies of the guidance 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; or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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.

FOR FURTHER INFORMATION CONTACT: