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.

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, HHHS.

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 guidelines for the design of BE studies to support abbreviated new drug applications (ANDAs) to support abbreviated new drug applications. In the Federal Register of May 31, 2007, FDA announced the availability of a draft guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE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 As described in that draft guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to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 guidance recommendations, either new or revised, that have been posted on the Federal Register’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 Hemiﬁbramate; Valsartan
Altretamine
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)
Benzagril HCl
Benzoxy Peroxide Clindamycin Phosphate (multiple RLDs)
Benzoxy Peroxide; Erythromycin (multiple RLDs)
Betamethasone Acetate; Sodium Phosphate
Betamethasone Dipropionate; Calcipotriene
Hydrate (multiple RLDs)
Betamethasone Dipropionate; Clostrimazole
Betamethasone; Clostrimazole
Bexarotene
Bosantan
Buprenorphine HCl
Buprenorphine HCl; Naloxone HCl
Bupropion HBr
Bupropion HCl
Buspirone
Butocanazole Nitrate (multiple RLDs)
C
Calcipotriene (multiple RLDs)
Carbidoza; Levodopa
Carisoprodol
Carvedilol Phosphate
Cefadroxil; Cefadroxil Hemihydrate
Cefditoren Pivoxil
Cefixime
Cefuroxime Axetil (multiple RLDs)
Cetirizine HCl
Chlorambucil
Chlorpheniramine Polistirex; Hydrocodone Polistirex
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
- Bupropion HBr
- Calcipotriene
- Calcium Acetate
- Calcitriol
- Capecitabine (multiple RLDs)
- Celozitoren Pivoxil
- Ciclopirox
- Colesevelam HCl (multiple RLDs)
- Dutaravastatin
- Desogen; Ethinyl Estradiol
- Desvenlafaxine Succinate
- Diclofenac Sodium
- Docetaxel (multiple RLDs)
- Donepezil HCl (multiple RLDs)
- Emtricitabine
- Esomeprazole Magnesium
- Estradiol
- Ethinyl Estradiol; Ethynodiol Diacetate (multiple RLDs)
- Ethinyl Estradiol; Norethindrone
- Felbamate (multiple RLDs)
- Fentanyl
- Fentanyl Citrate
- Fluorouracil (multiple RLDs)
- Glyburide Metformin
- Granisetron HCl
- Labetalol HCl
- Lamotrigine (multiple RLDs)
- Lapatinib Ditosylate
- Levofoxacin
- Levonnorgestrel (multiple RLDs)
- Linezolid
- Memantine HCl
- Mercaptopurine (multiple RLDs)
- Metformin HCl (multiple RLDs)
- Minoxidil
- Morphine
- N
- Nebivolol
- Niacin
- Nilutamide
- Nitroglycerin
- Omeprazole
- Orlistat (multiple RLDs)
- Oxymorphone HCl
- Prednisolone
- Progestrone
- R
- Rivastigmine
- Rivastigmine Tartrate
- Ropinirole
- S
- Scopolamine
- Sevelamer Carbonate (multiple RLDs)
- Sevelamer HCl (multiple RLDs)
- Sirolimus
- Telmisartan
- Tiagabine HCl
- Topiramate
- Tranexam Acid
- Triamcinolone Acetonide (multiple RLDs)
- Varenicline Tartrate
- Venlafaxine 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/ default.htm or http://www.regulations.gov.


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 guidelines 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: