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 In the **Federal Register** of May 31, 2007, FDA announced the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' explaining the process that would be used to make product-specific BE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

Atazanavir Sulfate
Atomoxetine HCl
Atorvastatin Calcium

**B**
Benzonatate
Benzphetamine HCl
Bicalutamide
Bisoprolol Fumarate
Bisoprolol Fumarate; Hydrochlorothiazide

**C**
Candesartan Cilexetil
Carbamazepine
Carvedilol
Cefditoren Pivoxil
Cetirizine HCl
Cevimeline HCl
Cilostazol
Cinacalcet HCl
Clarithromycin
Clonidine HCl

**D**
Danazol
Darifenacin HBr
Deferasirox
Desloratadine (multiple dosage forms)
Dextromethorphan Polistirex
Diclofenac Sodium; Misoprostol
Dicloxacillin Sodium
Didanosine (multiple dosage forms)
Digoxin
Dipyridamole
Divalproex Sodium
Dofetilide
Donepezil HCl (multiple dosage forms)
Doxazosin Mesylate
Drospirenone; Estradiol
Duloxetine HCl
Dutasteride

**E**
Efavirenz (multiple dosage forms)
Emtricitabine
Entacapone
Entecavir
Eplerenone
Erlotinib HCl
Escitalopram Oxalate
Esomeprazole Magnesium
Etidronate Disodium
Exemestane

**F**
Famotidine (multiple dosage forms)
Fenofibrate (multiple dosage forms)
Fluconazole
Fluoxetine HCl; Olanzapine
Fosamprenavir Calcium
Fosinopril Sodium

**G**
Gabapentin
Gemifloxacin Mesylate
Glimepiride
Glipizide; Metformin HCl
Glyburide; Metformin HCl
Granisetron HCl

**H**
Hydrochlorothiazide
Hydrochlorothiazide; Irbesartan
Hydrochlorothiazide; Lisinopril
Hydrochlorothiazide; Losartan Potassium

Hydrochlorothiazide; Olmesartan Medoxomil

**I**
Ibandronate Sodium
Indinavir Sulfate
Irbesartan
Isosorbide Mononitrate
Isradipine (multiple dosage forms)

**L**
Lamivudine
Lamivudine; Zidovudine
Lamotrigine (multiple dosage forms)
Levonorgestrel
Liothyronine Sodium
Loratadine
Losartan Potassium

**M**
Mefloquine HCl
Meloxicam (multiple dosage forms)
Mercaptopurine
Metformin HCl
Metformin HCl; Pioglitazone HCl
Miglustat
Mirtazapine
Modafinil
Moexipril HCl

**N**
Nabumetone
Nateglinide
Nelfinavir Mesylate
Nevirapine

**O**
Olanzapine
Olmesartan Medoxomil
Olsalazine Sodium
Omeprazole
Omeprazole Magnesium
Omeprazole; Sodium Bicarbonate
Ondansetron
Ondansetron HCl
Oxcarbazepine (multiple dosage forms)

**P**
Pantoprazole Sodium
Perindopril Erbumine
Phenytoin
Phenytoin Sodium (multiple dosage forms)

Pilocarpine HCl
Pravastatin Sodium

**Q**
Quetiapine Fumarate
Quinapril HCl

**R**
Raloxifene HCl
Ramipril
Ribavirin (multiple dosage forms)
Rifampin
Riluzole
Risedronate Sodium; Calcium Carbonate
Ritonavir
Rizatriptan Benzoate
Rosiglitazone Maleate
Rosuvastatin Calcium

**S**
Sertraline HCl
Sibutramine HCl
Sildenafil Citrate
Simvastatin
Stavudine
Sulfamethoxazole; Trimethoprim
Sumatriptan Succinate

**T**
Tamsulosin HCl
Telithromycin
Telmisartan
Terazosin HCl
Terbinafine HCl
Testosterone
Ticlopidine HCl
Tizanidine HCl
Tolterodine Tartrate
Torsemide
Tramadol HCl
Tramadol HCl; Acetaminophen
Trandolapril
Triamterene

**V**
Valacyclovir HCl
Valsartan
Vardenafil HCl
Verapamil HCl (multiple reference listed drug (RLDs))
Voriconazole

**Z**
Zaleplon
Zidovudine (multiple dosage forms)
Ziprasidone 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.

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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.

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Dated: May 27, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9–13261 Filed 6–5–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301–496–7057; *fax:* 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Interactive Venn Diagram Software Designed for Microarray Analysis**

*Description of Technology:* Multiple conditions from any source, but designed for experiments involving microarrays, will produce (significant gene lists for arrays) lists from each condition, thus multiple lists. This Java® based software provides investigators with a method of displaying multiple conditions in a single graphic along with producing a text output of genes that are the product of these conditional intersections along with each conditions unique list. A standard Venn diagram is limited to only display three (3) comparisons; this software can display any number of comparisons and will automatically create lists from all intersections even if not able to be displayed along with each conditions unique list.

*Applications:*

- Microarray analysis.
- Genomics.
- Bioinformatics.
- Any environment creating multiple lists (Business, Accounting, Inventory Control, etc.).

*Inventor:* Daniel E. Sturdevant (NIAID).

*Patent Status:* HHS Reference No. E–189–2009/0—Research Tool. Patent protection is not being pursued for this technology.

*Licensing Status:* Available for licensing.

*Licensing Contact:* Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

**Axenically-Produced *Coxiella burnetii* and Methods for Producing Axenic *Coxiella burnetii***

*Description of Technology: Coxiella burnetii* is the causative agent of Q (Query) fever. Currently, there is a need for a safe Q fever vaccine. It is anticipated that axenically-produced *C. burnetii,* which is free of host cell related impurities, could provide either the basis for a whole-cell Q fever vaccine or advance the development of a safe recombinant Q fever vaccine. Currently, there are no licensed Q-fever vaccines except for a whole-cell, formalin inactivated, vaccine which is available in Australia (Q–Vax). Individuals with a previous exposure to *C. burnetii* may, however, have a severe allergic reaction to this vaccine and other individuals may experience a headache or flu-like symptoms after vaccination. It is anticipated that axenically-produced *C. burnetii* could provide the basis for a less reactogenic whole-cell vaccine or facilitate the development of a recombinant vaccine that does not cause an allergic reaction. Additionally, the inability to propagate obligate intracellular pathogens under axenic (host cell-free) culture conditions imposes severe experimental constraints that have negatively impacted progress in understanding pathogen virulence and disease mechanisms.

Q fever is a zoonotic disease and farm animals, pets, and rodents are significant reservoirs for *C. burnetii. C. burnetii* persists in the soil for a long time and typically humans are exposed to Q fever by the inhalation of the bacterium deposited with animal waste such as urine, feces, and amniotic fluid. The epidemiology of Q fever is diverse and the disease does not discriminate between developed and developing countries. Additionally, urban outbreaks have been known to occur due to windborne *C. burnetii. C. burnetii* is listed as a select agent by the Department of Health and Human Services (HHS) because of its potential as an agent of bioterrorism. Deployed military personnel are also at risk of contracting Q fever and thousands of cases of Q fever have been reported among military personnel since the disease was first reported in the 1930s.

*Advantages:*

- The ability to propagate, previously unpropagatable, *C. burnetii* without a hostcell.
- The ability to study *C. burnetii* virulence using axenic conditions or conditions free of host cell-related impurities.
- This technology is ready for use in drug/vaccine discovery, production, and development.
- Potential licensees of this invention include companies that are: 1) seeking vaccine production platforms based on host cell-free (axenic) media, 2) seeking to develop recombinant vaccines for obligate, intracellular, bacteria; or 3) seeking to lower costs and ease scale-up would be potential licensees of this technology.

*Development Status:* This technology has been demonstrated with *C. burnetii.* Currently, the inventors are testing this technology for support of axenic growth of other obligate, intracellular, bacteria of public health significance.

*Inventors:* Robert A. Heinzen, Anders Omsland, Diane C. Cockrell, Dale Howe (NIAID).

*Publication:* A Omsland et al. Host cell-free growth of the Q fever bacterium *Coxiella burnetii*. Proc Natl Acad Sci USA. 2009 Mar 17;106(11):4430–4434.

*Patent Status:* U.S. Provisional Application No. 61/154,330 filed 20 Feb 2009 (HHS Reference No. E–114–2009/0–US–01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Peter A. Soukas, J.D.; 301–435–4646; *soukasp@mail.nih.gov.*