Fosamprenavir Calcium
Fosinopril Sodium; Hydrochlorothiazide

G
Gabapentin (multiple dosage forms)
Galantamine HBr
Ganciclovir
Gemifloxacin Mesylate
Glimepiride
Glipizide; Metformin HCl
Glyburide; Metformin HCl
Granisetron HCl

H
Hydrochlorothiazide
Hydrochlorothiazide; Lisinopril
Hydrochlorothiazide; Losartan Potassium
Hydrochlorothiazide; Moexipril HCl
Hydrochlorothiazide; Olmesartan Medoxomil
Hydrochlorothiazide; Valsartan

I
Ibandronate Sodium
Ibuprofen; Pseudoephedrine HCl
Indinavir Sulfate
Irbesartan
Isosorbide Mononitrate
Isradipine (multiple dosage forms)
Itraconazole

L
Lamivudine
Lamivudine; Zidovudine
Lamotrigine (multiple dosage forms)
Leflunomide
Liothyronine Sodium
Losartan Potassium

M
Mefloquine HCl
Meloxicam (multiple dosage forms)
Mercaptopurine
Mesalamine
Metaxalone
Metformin HCl
Metformin HCl; Pioglitazone HCl
Miglustat
Mirtazapine
Modafinil
Moexipril HCl
Montelukast Sodium
Morphine Sulfate
Mycophenolate Mofetil
Mycophenolate Mofetil HCl

N
Nabumetone
Nateglinide
Nelfinavir Mesylate
Nevirapine

O
Olanzapine
Olmesartan Medoxomil
Olsalazine Sodium
Omeprazole (multiple dosage forms)
Omeprazole Magnesium
Ondansetron (multiple dosage forms)
Oxcarbazepine (multiple dosage forms)

P
Pantoprazole Sodium
Perindopril Erbumine
Pilocarpine HCl
Pravastatin Sodium

Q
Quetiapine Fumarate
Quinapril HCl

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

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

T
Tacrolimus
Tadalafil
Tamsulosin HCl
Telithromycin
Telmisartan
Terbinafine HCl
Testosterone
Ticlopidine HCl
Tizanidine HCl
Tolterodine Tartrate
Topiramate (multiple dosage forms)
Torsemide
Tramadol HCl
Tramadol HCl; Acetaminophen
Trandolapril
Triamterene

V
Valacyclovir HCl
Valsartan
Vardenafil HCl
Venlafaxine HCl
Verapamil HCl (multiple dosage forms)
Voriconazole

Z
Zaleplon
Zidovudine (multiple dosage forms)
Ziprasidone HCl
Zolpidem Tartrate

These draft guidances are available on the CDER guidance page and may be viewed by clicking on the URL associated with the draft ''Bioequivalence Recommendations for Specific Products'' guidance on the CDER guidance page or on the Office of Generic Drugs Page (see *www.fda.gov/cder/ogd/index.htm*). Users can also search for a specific product BE recommendation using the search tool on the CDER guidance page.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances represent the agency's current thinking on the design of product-specific bioequivalence studies to support ANDAs. Guidance does not create or confer any rights for or on any person and does 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.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft product-specific BE recommendations at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10491 Filed 5–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0169]

Draft Guidance for Industry on Bioequivalence Recommendations for Specific Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that describes a new process for making available recommendations on how to design product-specific bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). Under this process, applicants planning to carry out such studies in support of their ANDAs will be able to access BE study guidance on the FDA Web site. FDA believes that making this information available on the Internet

will streamline the guidance process and will provide a meaningful opportunity for the public to consider and comment on product-specific BE study recommendations. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the first group of draft product-specific BE recommendations.

DATES: Submit written or electronic comments on the draft guidance by August 29, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0495.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products.'' To receive approval for an ANDA, an applicant generally must demonstrate, among other things, that its product has the same active ingredient, dosage form, strength, route of administration and conditions of use as the listed drug, and that the proposed drug product is bioequivalent to the reference listed drug (21 U.S.C. 355(j)(2)(A); 21 CFR 314.94(a)). Bioequivalent drug products show no significant difference in the rate and extent of absorption of the therapeutic ingredient (21 U.S.C. 355(j)(8); 21 CFR 320.1(e)). BE studies are undertaken in support of ANDA submissions with the goal of demonstrating BE between a proposed generic drug product and its reference listed drug. The regulations governing BE are provided at 21 CFR in part 320.

Previously, the Office of Generic Drugs (OGD) has provided information on how to design BE studies for specific products only when asked for assistance by individual applicants. In most cases, the requested information was not available anywhere else, and, in some cases, OGD performed its own research before responding to an applicant's request for information. In many cases, FDA responded to individual applicants in letter format after specific recommendations were prepared by individuals within the Center for Drug Evaluation and Research (CDER). With the increasing number of both ANDA submissions and requests for BE information during the last few years, this approach has become inefficient and extremely time consuming for the agency.

As a result, after exploring various mechanisms that would allow us to conserve our resources while responding to the needs of industry and other interested persons, OGD has developed a new approach to making guidance available on product-specific BE studies. As before, BE recommendations will be developed by the agency based on its understanding of the characteristics of the listed drug, information derived from published literature, agency research, and consultations within different offices in CDER as needed based upon the novelty or complexity of the BE considerations. FDA proposes that, once drafted, product-specific BE recommendations will be made available through the process described in the guidance.

II. Procedures for Making BE Recommendations Available

To streamline the process for making guidance available to the public on how to design product-specific BE studies, the agency intends to use the following process:

- Product-specific BE recommendations will be developed and posted on the CDER guidance page at *http://www.fda.gov/cder/index.html* in draft to facilitate public consideration and comment.
- The recommendations can be viewed by clicking on the URL associated with this guidance on the CDER guidance page (*http://www.fda.gov/cder/index.html*) or on the OGD page (see *www.fda.gov/cder/ogd/index.htm*). Users can also search for a specific product BE recommendation using the search tool on the guidance page.
- Newly posted draft and final BE recommendations will be announced in the New/Revised/Withdrawn list, which is posted monthly on the CDER guidance page.
- The agency will issue a notice in the **Federal Register** announcing the availability on the FDA Web site of new product-specific draft and final BE recommendations. The notice will identify a comment period for the recommendations.
- Comments on product-specific BE recommendations will be considered in developing final BE recommendations.
- The BE recommendations will be revised as appropriate to ensure that the most up-to-date BE information is available to the public.

FDA has decided to make the first group of BE recommendations available concurrently with the issuance of this draft guidance document. A notice of availability of the first group of draft product-specific BE recommendations is also being published today. It includes a list of the drug products for which draft BE recommendations are available. Comments on the product-specific draft guidances are requested within 120 days.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on a new process for making available to sponsors FDA guidance on how to design product-specific bioequivalence studies to support ANDAs. It does not create or confer any rights for or on any person and does 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.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. 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.fda.gov/ohrms/dockets/default.htm*.

Dated: May 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10492 Filed 5–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Jackson Heart Study (JHS)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 25, 2006, pages 62476–62477, and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Jackson Heart Study (JHS). *Type of Information Collection Request:* Extension of a currently approved collection (OMB NO. 0925–0491). *Need and Use of Information Collection:* This project involves annual follow-up by telephone of participants in the JHS, review of their medical records, and interviews with doctors and family to identify disease occurrence. Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in African American men and women. *Frequency of Response:* One time. *Affected Public:* Individuals or households; Businesses or other for profit; Small businesses or organizations. *Type of Respondents:* Individuals or households; Businesses or other for profit; not-for-profit institutions. The annual reporting burden is as follows: *Estimated Number of Respondents:* 600; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response:* 0.5 and *Estimated Total Annual Burden Hours Requested:* 300. The annualized cost to respondents is estimated at $9,500. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATE OF ANNUAL HOUR BURDEN

Type of response	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Morbidity & Mortality AFU 3rd Party/Next-of-kin decedents	300	1	0.5	150
Morbidity & Mortality AFU 3rd Party Physicians	300	1	0.5	150
Total	600			300

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Cheryl Nelson, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892–7934, or call non-toll-free number 301–435–0451 or E-mail your request, including your address to: *NelsonC@nhlbi.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: May 22, 2007.

Peter Savage,

Acting Director.

Dated: May 22, 2007.

Suzanne A. Freeman,

Project Clearance Officer.

[FR Doc. 07–2698 Filed 5–30–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive License: Developing, Manufacturing and Selling Instruments, Reagents and Related Products and Providing Services Involving Sequencing Nucleic Acids, Including Without Limitations Diagnostic Devices and Services

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a co-exclusive license to practice the invention embodied in Patent Applications U.S. 60/151,580, filed August 29, 1999; PCT/US00/23736, filed August 29, 2000, U.S. 6,982,146 issued January 3, 2006, and USSN 11/204,367, filed August 12, 2005; entitled ''High Speed Parallel Molecular Nucleic Acid Sequencing'', to Invitrogen Corporation having a place of business in Carlsbad,