DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999D–1651] (formerly Docket No. 99D–1651)

Guidance for Industry: Chemistry, Manufacturing, and Control Changes to an Approved New Animal Drug Application or Abbreviated New Animal Drug Application

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#83) entitled ''Chemistry, Manufacturing, and Control Changes to an Approved NADA or ANADA.'' This guidance is intended to provide recommendations to holders of new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) on how they should report certain changes to such applications, in accordance with the final regulation, 21 CFR 514.8, which was issued in the **Federal Register** of December 13, 2006 (71 FR 74766).

DATES: Comments on agency guidances are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written comments on the guidance document 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*.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Jr., Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–6956, e-mail: *dennis.bensley@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 1, 1999 (64 FR 53281), FDA published a proposed rule to implement section 506A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356a) for NADAs and ANDAs. In that same issue of the **Federal Register** (64 FR 53393), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Chemistry, Manufacturing, and Control Changes to an Approved NADA or ANADA,'' giving interested persons until December 15, 1999, to submit comments. FDA considered all comments received and, where appropriate, incorporated them into the guidance.

This guidance covers recommended reporting categories for various postapproval manufacturing changes and provides recommendations to holders of NADAs and ANADAs on how they should report such changes in accordance with the final regulation, 21 CFR 514.8, issued in the **Federal Register** of December 13, 2006 (71 FR 74766). Recommendations are provided for postapproval changes in: (1) Components and composition, (2) manufacturing sites, (3) manufacturing process, (4) specifications, (5) container closure system, as well as (6) miscellaneous changes and (7) multiple related changes. This guidance does not provide recommendations on the specific information that should be developed by an applicant to assess the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a drug as these factors may relate to the safety or effectiveness of the drug. An applicant should consider all relevant FDA guidance documents for recommendations on the information that should be submitted to support a given change.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on the topic. 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 method may be used as long as it satisfies the requirements of applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in sections II through XI of the guidance have been approved under OMB Control No. 0910–0600.

IV. Comments

As with all of FDA's guidance, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

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 should be identified with the full title of the guidance document and the docket number found in brackets in the heading of this document. A copy of the document 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 a copy of the guidance document entitled ''Chemistry, Manufacturing and Control Changes to an Approved NADA or ANADA'' from the CVM home page at *http://www.fda.gov/cvm*.

Dated: May 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10515 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–0168]

Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces the availability of draft guidances for industry that describe recommendations on how to design bioequivalence (BE) studies for 200 specific drug products to support abbreviated new drug applications (ANDAs). These draft guidances are being made available

concurrently with the publication of a draft guidance for industry entitled ''Draft Guidance for Industry—Bioequivalence Recommendations for Specific Products'' (product specific BE recommendations). This draft guidance describes the new process for making available guidance on product-specific BE studies. Under the process described in the draft guidance, draft and final product-specific BE study guidance will be made available on the FDA Web site. FDA believes that making this information available on the Internet will streamline the guidance process and 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 a related guidance document entitled ''Draft Guidance for Industry—Bioequivalence Recommendations for Specific Products.''

DATES: Submit written or electronic comments on the draft guidances by September 28, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of draft product-specific BE study guidances 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

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.

The draft guidance entitled ''Bioequivalence Recommendations for Specific Products'' describes the following process for making available draft and final product-specific BE recommendations:

- FDA will develop product-specific BE recommendations and post them on the Center for Drug Evaluation and Research (CDER) guidance page (*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 the ''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.
- Newly posted draft and final BE recommendations will be announced in the ''Newly Added Guidance Documents'' 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 is making the first group of draft product-specific BE recommendations available concurrently with the issuance of the draft guidance document describing the process.

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

The FDA is making available draft recommendations for drug products containing the following active ingredients:

A

Abacavir Sulfate
Abacavir Sulfate; Lamivudine; Zidovudine
Acamprosate Calcium
Acitretin
Acyclovir
Almotriptan Malate
Alosetron HCl
Alprazolam
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
Candesartan Cilexetil; Hydrochlorothiazide
Carbamazepine
Carbidopa; Entacapone; Levodopa
Carvedilol
Cefditoren Pivoxil
Celecoxib
Cetirizine HCl
Cevimeline HCl
Cilostazol
Cinacalcet HCl
Clarithromycin
Clonidine HCl
Clopidogrel

D

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

E

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

F

Famotidine (multiple dosage forms)
Felbamate (multiple dosage forms)
Fenofibrate
Fexofenadine HCl (multiple dosage forms)
Flavoxate HCl
Fluconazole
Fluoxetine HCl; Olanzapine

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.

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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