lenders may have excessive delinquencies and defaulted loans.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Disclosure: Repayment Schedule HRSA 502–1,2	8	396	3,168	0.50	1,584
Reporting: Call Report HRSA 512	13	4	52	0.75	39
Total Reporting and Disclosure	21		3,220		1,623

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: November 24, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9–28696 Filed 11–30–09; 8:45 am]

BILLING CODE 4165–15–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 In the **Federal Register** of May 31, 2007, FDA announced the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' explaining the process that would be used to make product-specific BE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: Submit written or electronic comments on the draft and revised draft product-specific BE recommendations listed in this notice by February 1, 2010.

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 draft 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 draft guidance 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 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 June 8, 2009 (74 FR 27146). This notice announces draft product-specific recommendations, either new or revised, that have been posted on FDA's Web site in the period from November 1, 2008, through December 1, 2009.

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

Adapalene (multiple reference listed drugs (RLDs))
Adapalene; Benzoyl Peroxide
Alendronate Sodium; Cholecalciferol
Aliskiren Hemifumarate
Aliskiren Hemifumarate; Hydrochlorothiazide
Allopurinol
Ambrisentan
Amlodipine Besylate; Atorvastatin Calcium
Atenolol

B

Bromfenac Sodium
Bromocriptine
Budesonide

C

Calcium Acetate
Cephalexin
Chlorpheniramine Polistirex; Hydrocodone Polistirex
Ciprofloxacin
Clonidine
Clotrimazole (multiple RLDs)

D

Desmopressin Acetate
Desogestrel; Ethinyl Estradiol (multiple RLDs)
Desvenlafaxine Succinate
Dextroamphetamine Sulfate
Dextromethorphan Hydrobromide; Guaifenesin
Diclofenac Sodium (multiple RLDs)
Doxycycline Hyclate
Drospirenone; Ethinyl Estradiol

E

Eletriptan Hydrobromide

Estradiol (multiple RLDs)
Ethinyl Estradiol; Levonorgestrel (multiple RLDs)
Ethinyl Estradiol; Norelgestromin
Ethinyl Estradiol; Norethindrone Acetate (multiple RLDs)
Ethinyl Estradiol; Norgestrel (multiple RLDs)

F
Famotidine
Felodipine
Fenoprofen Calcium
Fentanyl
Fexofenadine HCl
Fexofenadine; Pseudoephedrine (multiple RLDs)
Fludrocortisone Acetate

G
Glimepiride; Pioglitazone HCl
Glycopyrrolate
Guaifenesin; Pseudoephedrine HCl

H
Haloperidol
Hydrocodone Bitartrate; Acetaminophen
Hydroxyzine Pamoate (multiple RLDs)

I
Imatinib Mesylate

L
Lansoprazole
Levetiracetam
Linezolid
Loratadine

M
Meprobamate
Metformin HCl (multiple RLDs)
Metformin HCl; Repaglinide
Methotrexate Sodium (multiple RLDs)
Metoclopramide HCl
Miconazole Nitrate (multiple RLDs)
Mycophenolic Acid

N
Nadolol
Naltrexone
Niacin
Nifedipine
Nilutamide
Nisoldipine
Nitazoxanide
Nitrofurantoin
Nitrofurantoin Macrocrystalline
Norethindrone
Norethindrone Acetate

O
Oxybutynin Chloride

P
Phendimetrazine Tartrate (multiple RLDs)
Phentermine HCl (multiple RLDs)
Phytonadione
Pramipexole Dihydrochloride
Prednisolone
Pregabalin
Propafenone HCl
Pyridostigmine Bromide

R
Raltegravir Potassium
Ramelteon
Raniditine (multiple RLDs)
Rasagiline Mesylate
Rivastigmine Tartrate

S
Scopolamine
Selegiline
Sodium Phenylbutyrate (multiple RLDs)
Sorafenib Tosylate

T
Tamoxifen Citrate
Telbivudine
Temazepam
Terbinafine HCl
Toremifene Citrate
Trandolapril; Verapamil HCl
Triamcinolone Acetonide (multiple RLDs)

V
Voriconazole

Z
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 FDA's Web site:

A
Azacitidine

B
Busulfan

C
Carbidopa; Entacapone; Levodopa

D
Darunavir Ethanolate
Desogestrel; Ethinyl Estradiol
Doxercalciferol

E
Ethinyl Estradiol; Norethindrone (multiple RLDs)

F
Fluoxetine HCl; Olanzapine

H
Hydrochlorothiazide; Lisinopril

I
Ibuprofen

L
Lansoprazole
Lovastatin; Niacin

M
Methylprednisolone Acetate
Melphalan

N
Nabilone

O
Omeprazole; Sodium Bicarbonate

Q
Quetiapine Fumarate

R
Risedronate Sodium

S
Sevelamer Carbonate
Sevelamer HCl
Sildenafil Citrate

T
Temozolomide
Topiramate
Tacrolimus

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 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: November 20, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–28593 Filed 11–30–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0466]

Draft Compliance Policy Guide Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase Activity (Compliance Policy Guide 7106.08); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft Compliance Policy Guide Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase Activity (CPG 7106.08) (the draft CPG). The draft CPG, when finalized, will provide guidance for FDA staff on its enforcement policies for pathogens and other indicators of inadequate pasteurization or post-pasteurization contamination of dairy products.

DATES: Although you can comment on any CPG at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on the draft CPG before it begins work on the final version of the CPG, submit written or electronic comments on the draft CPG by February 1, 2010.

ADDRESSES: Submit written comments on the draft CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft CPG to *http://www.regulations.gov*. Submit written requests for single copies of the draft CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

FOR FURTHER INFORMATION CONTACT: Monica Metz, Center for Food Safety and Applied Nutrition (HFS–316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2041.

SUPPLEMENTARY INFORMATION:

I. Background

The draft CPG is intended to provide guidance for FDA staff regarding pathogens and indicators of inadequate pasteurization or post-pasteurization contamination of dairy products. The draft CPG outlines regulatory enforcement policies for FDA staff to use to initiate legal action recommendations based on analytical determinations that a dairy product contains a pathogenic micro-organism (i.e., *Salmonella* species, enterohemorrhagic *Escherichia coli* (EHEC) O157:H7, *Campylobacter jejuni*, *Yersinia enterocolitica*, or *Clostridium botulinum*); toxins produced by *Clostridium botulinum*, enterotoxigenic *Staphylococcus*, or *Bacillus cereus*; *Staphylococcus aureus*; *Bacillus cereus*, nontoxigenic *Escherichia coli*; or alkaline phosphatase. The draft CPG also contains information that may be useful to the regulated industry and to the public.

FDA is issuing the draft CPG as level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent the agency's current thinking on pathogens and indicators of inadequate pasteurization or post-pasteurization contamination of dairy products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft CPG at *http://www.fda.gov/ora/compliance_ref/cpg/default.htm* or *http://www.regulations.gov*.

Dated: November 24, 2009.

Michael A. Chappell,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. E9–28756 Filed 11–30–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0524]

Guidance for Industry on Listing of Ingredients in Tobacco Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Listing of Ingredients in Tobacco Products.'' The guidance document is intended to assist persons making tobacco product ingredient submissions to FDA under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Listing of Ingredients in Tobacco Products'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit written comments on the 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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michele Mital, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 301–796–4800, *Michele.Mital@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: