TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity	Number of respondents	Number of disclosures per respondent [2]	Total annual disclosures	Average burden per disclosure	Total hours
Total	.....	.....	.....	.....	5,560

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Number has been rounded to the nearest tenth.

The labeling requirements of section 403(y) of the FD&C Act became effective on December 22, 2007, although FDA exercised enforcement discretion until September 30, 2010, to enable all firms to meet the labeling requirements for dietary supplements. FDA estimates that all labels required to include the domestic address or telephone number pursuant to section 403(y) of the FD&C Act have been revised by the effective date. Thus, in succeeding years, the Agency estimates that the burden hours associated with the labeling requirements of section 403(y) of the FD&C Act and the Agency's recommendations on the use of an explanatory statement will apply only to new product labels. Based on the A.C. Nielsen Sales Scanner Data, FDA estimated that the number of dietary supplement SKUs for which sales of the products are greater than zero is 55,600. Assuming that the flow of new products is 10 percent per year, then approximately 5,560 new dietary supplement products will come on the market each year. FDA also estimates that there are about 1,460 dietary supplement manufacturers, re-packagers, re-labelers, and holders of dietary supplements. Assuming the approximately 5,560 new products are split equally among the firms, then each firm would prepare labels for close to four new products per year (5,560 new products/1,460 firms is approximately 3.8 labels per firm). Thus, the estimated total annual disclosures are 5,560 (1,460 firms × 3.8 labels per year = 5,560).

The Agency expects that firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed on their product labels. Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 0.5 hour per product to comply with the requirement to include the domestic address or telephone number pursuant to section 403(y) of the FD&C Act. The total hour burden of this task is shown in row 1 of table 1.

FDA estimates that all firms will include an explanatory statement on the label, which lets consumers know the purpose of the domestic address or telephone number on the label of the dietary supplement product. Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 0.5 hour per product to comply with the Agency's recommendations on the use of an explanatory statement. The total hour burden of this task is shown in row 2 of table 1.

The total reporting hour burden is 5,560 hours, which equals the burden for the required domestic address or telephone (2,780) plus the burden for the explanatory statement before the domestic address or telephone number (2,780).

Dated: June 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14487 Filed 6–13–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

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 June 11, 2010 (75 FR 33311), FDA announced the availability of a 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. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by August 13, 2012.

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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations 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: K. Geoffrey Wu, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9326.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010, FDA announced the availability of a 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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* As described in that 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 March 28, 2012 (77 FR 18827). This notice announces draft product-specific recommendations, either new or revised, that are being posted on FDA's Web site concurrently with publication of this notice.

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

FDA is announcing new draft product-specific BE recommendations for drug products containing the following active ingredients:

A
- Aliskiren hemifumarate; amlodipine besylate
- Alvimopan
- Azilsartan medoxomil

B
- Bacitracin
- Boceprevir

C
- Cefpodoxime proxetil (multiple reference listed drugs (RLDs))
- Cefprozil (multiple RLDs)
- Cetirizine HCl
- Ciprofloxacin HCl; hydrocortisone
- Clomiphene citrate

D
- Dabigatran etexilate mesylate
- Dexamethasone; tobramycin
- Dinoprostone
- Diphenhydramine; ibuprofen

E
- Erythromycin

F
- Famotidine; ibuprofen

G
- Gabapentin enacarbil

I
- Itraconazole

K
- Ketoconazole

L
- Lacosamide

M
- Malathion
- Morphine sulfate; naltrexone HCl

P
- Podofilox

R
- Rotigotine
- Rufinamide

T
- Tapentadol HCl
- Tetrabenazine

Z
- Zolpidem tartrate

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

FDA is announcing revised draft product-specific BE recommendations for drug products containing the following active ingredients:

D
- Dexamethasone; tobramycin (multiple RLDs)

E
- Everolimus

L
- Loteprednol etabonate
- Loteprednol etabonate; tobramycin

S
- Sorafenib tosylate

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, please go to *http://www.regulations.gov* and enter docket number FDA–2007–D–0369.

These draft and revised draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These 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**) either electronic or written comments on any of the specific BE recommendations posted on FDA's Web site. Identify comments with the docket number found in brackets in the heading of this document. The guidances, 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: June 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14477 Filed 6–13–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0146]

Guidance for Industry on Irritable Bowel Syndrome—Clinical Evaluation of Drugs for Treatment; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of May 31, 2012 (77 FR 32124). The document announced the availability of a guidance for industry entitled ''Irritable Bowel Syndrome—Clinical Evaluation of Drugs for Treatment.'' The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3208, Silver Spring, MD 20993–0002, 301–796–9148.

SUPPLEMENTARY INFORMATION: In FR Doc. 2012–13143, appearing on page 32124 in the **Federal Register** of Thursday, May 31, 2012, the following correction is made:

1. On page 32124, in the first column, in the headings section of the document, ''[Docket No. FDA–2012–D–0146]'' is corrected to read ''[Docket No. FDA–2010–D–0146]''.

Dated: June 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14485 Filed 6–13–12; 8:45 am]

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