

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.

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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:

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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.

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