Mirabegron
S
Sodium ferric gluconate
T
Timolol maleate
Trientine

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:

A
Albuterol sulfate (multiple reference listed drugs)
Ambrisentan
C
Carbidopa; Entacapone; Levodopa
Colesevelam
D
Dexamethasone; Tobramycin (multiple reference listed drugs and dosage forms)
Didanosine
Drospirenone; Estradiol
E
Entacapone
F
Fentanyl citrate
I
Isotretinoin
M
Minocycline hydrochloride
P
Phentermine hydrochloride; Topiramate
T
Tenofovir disoproxil fumarate
Topiramate (multiple reference listed drugs and dosage forms)

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 either electronic comments on any of the specific BE recommendations posted on FDA's Web site to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. 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, and will be posted to the docket at *http://www.regulations.gov*.

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 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14675 Filed 6–19–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0938]

Guidance for Industry; Guidance on Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance entitled ''ANDAs: Stability Testing of Drug Substances and Products.'' FDA is recommending generic drug manufacturers follow the stability testing recommendations in the International Conference on Harmonisation (ICH) guidances Q1A (R2) through Q1E. The use of these ICH recommendations will standardize FDA's stability testing policies, which will help make the abbreviated new drug application (ANDA) review process more efficient.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance 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 the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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: Radhika Rajagopalan, Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., MPN2, rm. 243, HFD–640, Rockville, MD 20855, 240–276–8546.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''ANDAs: Stability Testing of Drug Substances and Products.'' Because of increases in the number and complexity of ANDAs and FDA's desire to standardize generic drug review, FDA is recommending that the generic drug industry follow the approach in the following stability related ICH guidances: (1) ''Q1A (R2) Stability Testing of New Drug Substances and Products,'' November 2003; (2) ''Q1B Photostability Testing of New Drug Substances and Products,'' November 1996; (3) ''Q1C Stability Testing for New Dosage Forms,'' November 1996; (4) ''Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products,'' January 2003; and (5) ''Q1E Evaluation of Stability Data,'' June 2004. These guidances can be found on the FDA Guidances (Drugs) Web site under International Conference on Harmonisation—Quality at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065005.htm*. FDA also recommends that industry follow the ICH outlined definitions, glossaries, references, and attachments.

Although the ICH stability guidances were developed for new drug applications to ensure the stability of new drug substances and products, FDA believes the recommendations provided in the ICH guidances on stability testing also are appropriate for ANDAs. FDA is recommending that applicants follow the ICH stability guidances for all ANDA submissions under section 505(j) of the Federal Food Drug, and Cosmetic Act (21 U.S.C. 355(j)) and relying on drug master files.

This guidance also replaces stability study storage condition recommendations made by the Office of Generic Drugs (OGD) in an August 18, 1995, letter to all ANDA applicants.

That letter stated that OGD would accept ANDAs with the ICH recommended long-term room temperature conditions for stability studies, 25 ± 2° C, 60 ± 5 percent RH.

On September 25, 2012 (77 FR 58999), FDA announced the availability of draft guidance for industry on ''ANDAs: Stability Testing of Drug Substances and Products.'' The public comment period closed on December 24, 2012. We are finalizing the guidance with minor changes and intend to publish a draft guidance to address the public comments in a question-and-answer format in the near future.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this stability testing for generic drug substances and 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 alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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 and will be posted to the docket at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.regulations.gov* or *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*.

Dated: June 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14674 Filed 6–19–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Cardio-metabolic risk and epigenetic differences among children conceives by infertility.

Date: July 1, 2013.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To provide concept review.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Officer, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Rockville, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 14, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–14649 Filed 6–19–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; NIA DBSR DATASETS.

Date: July 11–12, 2013.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Alfonso Latoni, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7702, *Alfonso.Latoni@nih.gov*.

Name of Committee: National Institute on Aging Special Emphasis Panel; Osteoimmunology.

Date: July 11, 2013.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20814, (Telephone Conference Call).

Contact Person: Elaine Lewis, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7707, *elainelewis@nia.nih.gov*.

Name of Committee: National Institute on Aging Special Emphasis Panel; Treatment of Obesity in Older Adults.

Date: July 18, 2013.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20814, (Telephone Conference Call).

Contact Person: Elaine Lewis, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7707, *elainelewis@nia.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: June 14, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–14647 Filed 6–19–13; 8:45 am]

BILLING CODE 4140–01–P