identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–6759 for ''Establishing Effectiveness for Drugs Intended to Treat Male Hypogonadotropic Hypogonadism Attributed to Non-Structural Disorders.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 document.

FOR FURTHER INFORMATION CONTACT: Jeannie Roule, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5332, Silver Spring, MD 20993–0002, 301–796–3993.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Establishing Effectiveness for Drugs Intended to Treat Male Hypogonadotropic Hypogonadism Attributed to Non-Structural Disorders.'' This draft guidance is intended to assist sponsors in designing drug development programs to demonstrate effectiveness of drugs intended to treat male hypogonadotropic hypogonadism associated with obesity and other conditions that do not cause intrinsic damage to the hypothalamus or pituitary gland.

Male hypogonadism is characterized by serum testosterone concentrations below the lower limit of the normal range for young, healthy men with associated symptoms (*e.g.,* reduced libido) or signs (*e.g.,* loss of muscle mass with reduced muscle strength). Some men who have had normal puberty and sexual development are subsequently diagnosed with hypogonadotropic hypogonadism associated with obesity or other acquired conditions in the absence of intrinsic damage to the hypothalamus or pituitary. Although these men have serum testosterone concentrations below the lower limit of the normal range for young, healthy men, the associated symptoms often experienced in this population (*e.g.,* low energy, depressed mood) are nonspecific and cannot definitively be attributed to the low testosterone concentrations. In addition, it is unclear whether these testosterone concentrations—in the absence of intrinsic damage to the hypothalamus and pituitary gland—are inappropriately low and whether increasing testosterone concentrations in these men confers clinical benefit.

For these reasons, serum testosterone is not a validated surrogate endpoint for establishing efficacy in these patients, and sponsors would need to show that an increase in serum testosterone translates into improvement in how patients feel, function, or survive.

This draft guidance addresses the following topics in establishing effectiveness of drugs for this population:

- Identification of patients for inclusion in clinical trials and
- Efficacy endpoints.

This draft guidance is consistent with recommendations FDA received at the December 2014 advisory committee meeting on the appropriate indicated population for testosterone replacement therapy, and the December 2016 advisory committee meeting on hypogonadotropic hypogonadism.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on establishing effectiveness for drugs intended to treat male hypogonadotropic hypogonadism attributed to non-structural disorders. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: December 27, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–28337 Filed 1–2–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct; Correction

AGENCY: Office of the Secretary, HHS.

ACTION: Correction of notice.

SUMMARY: This document corrects an error that appeared in the notice published in the November 27, 2017, **Federal Register** entitled ''Findings of Research Misconduct.''

DATES:

Effective Date: January 3, 2018.

Applicability Date: The correction notice is applicable for the Findings of

Research Misconduct notice published on November 27, 2017.

FOR FURTHER INFORMATION CONTACT: Ms. Karen Gorirossi at 240–453–8800.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2017–25549 of November 27, 2017 (82 FR 56042–56043), there was a referencing error involving incorrect citation of a paper in the notice. The error is identified and corrected in the Correction of Errors section below.

II. Correction of Errors

In FR Doc. 2017–25549 of November 27, 2017 (82 FR 56042–56043), make the following corrections:

1. On page 56042, third column, in FR Doc. 2017–25549, last paragraph, lines 16–26, and page 56043, first paragraph, lines 1–5, delete ''Respondent engaged in research misconduct at ESOM and falsified RT–PCR data on Excel spreadsheets in the research record and in a figure generated from the false data included in a manuscript submitted to and withdrawn from *Scientific Reports* (''Immipramine Blue Sensitively and Selectively Targets FLT3–ITD Positive Acute Myeloid Leukemia Cells.'' *Scientific Reports* 7(1):4447, 2017 June 30; doi:10.1038/s41598–017–04796–1. PMID: 28667329. Submitted to *Scientific Reports* [withdrawn]; hereafter referred to as the ''*Scientific Reports* manuscript'')'' and replace with the following text: ''Respondent engaged in research misconduct at ESOM and falsified RT–PCR data on Excel spreadsheets in the research record and in a figure generated from the false data included in an unpublished manuscript submitted to and withdrawn from *Scientific Reports* [withdrawn]; hereafter referred to as the ''*Scientific Reports* manuscript.'' ''

2. On page 56043, first column, in FR Doc. 2017–25549, fourth paragraph (second bullet), lines 6–7, insert ''unpublished'' before ''*Scientific Reports*'' so that the text reads: ''included false data in the unpublished *Scientific Reports* manuscript.''

Dated: December 20, 2017.

Wanda K. Jones,

Interim Director, Office of Research Integrity.

[FR Doc. 2017–28409 Filed 1–2–18; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings will be open to the public as indicated below, 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.

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 Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: January 24, 2018.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Natcher Building (Natcher Conference Center), Conference Room E1/E2, 45 Center Drive, Bethesda, MD 20892.

Closed: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building (Natcher Conference Center), Conference Room E1/E2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Acting Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive, and Kidney Diseases, 6707 Democracy Blvd., Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council, Kidney, Urologic and Hematologic Diseases.

Date: January 24, 2018.

Open: 1:00 p.m. to 3:30 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Natcher Building (Natcher Conference Center), Conference Room F1/F2, 45 Center Drive, Bethesda, MD 20892.

Closed: 3:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building (Natcher Conference Center), Conference Room F1/F2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Acting Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Diabetes, Endocrinology and Metabolic Diseases.

Date: January 24, 2018.

Open: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate to review the Division's scientific and planning activities.

Place: National Institutes of Health, Natcher Building (Natcher Conference Center), Conference Room E1/E2, 45 Center Drive, Bethesda, MD 20892.

Closed: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building (Natcher Conference Center), Conference Room E1/E2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Acting Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive, and Kidney Diseases, 6707 Democracy Blvd., Room, 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Digestive Diseases and Nutrition.

Date: January 24, 2018.

Open: 1:00 p.m. to 2:30 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Natcher Building (Natcher Conference Center), Conference Room D, 45 Center Drive, Bethesda, MD 20892.

Closed: 2:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

*Place:*National Institutes of Health, Natcher Building (Natcher Conference Center), Conference Room D, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Acting Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive, and Kidney Diseases, 6707 Democracy Blvd. Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.