The study team will also collect classroom rosters from caregivers before and after the field test.

Respondents: Early care and education (ECE) setting representatives (*e.g.,* directors or owners), caregivers (in center-based and family child care settings), and professional development providers (*e.g.,* coaches).

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
ECE setting eligibility screener	745	1	.25	186
Caregiver background survey	300	1	.75	225
PD provider background survey	175	1	.50	88
Caregiver We Grow Together website user data pop-up questions	300	6	.17	306
PD provider We Grow Together website user pop-up questions	175	5	.10	88
Caregiver feedback survey	300	1	1.0	300
PD provider feedback survey	175	1	.75	131
Classroom roster	300	2	.08	48
PD provider training survey	175	1	.17	30

Estimated Total Annual Burden Hours: 1,402.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–28375 Filed 1–2–18; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6759]

Establishing Effectiveness for Drugs Intended To Treat Male Hypogonadotropic Hypogonadism Attributed to Non-Structural Disorders; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 provides key design considerations, including recommendations for patient enrollment criteria and efficacy endpoints, for clinical trials to establish effectiveness for 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. 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.

DATES: Submit either electronic or written comments on the draft guidance by March 5, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

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