FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of submission (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Supplements to applications approved 6/30/01 to 6/30/15 (§§ 314.70(b), 601.12(f)(1)).	390	26	10,140 (Submitted 3rd, 4th, and 5th years after 6/30/15).	120	1,216,800
Annual report submission of revised labeling for applications that contain a pregnancy category, approved before 6/30/01 (§§ 314.70(d), 601.12(f)(3)).	320	~17	5,500 (Submitted 3rd year after 6/30/15).	40	220,000
Total					1,436,800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of submission (21 CFR section)	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
New Drug Applications (NDAs)/Abbreviated New Drug Applications (ANDAs)/Biologics License Applications (BLAs)/efficacy supplements submitted on or after 6/30/15, including amendments to applications pending as of 6/30/15 (§§ 314.50) 314.60, 314.70(b), 601.2, 601.12(f)(1)).	390	~10	4,000 (Submitted during 10-year period after 6/30/15).	40	160,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that approximately 4,000 applications containing the subject labeling will be submitted by approximately 390 applicants and repackagers and relabelers to FDA over the 10-year period beginning June 30, 2015. This figure (4,000 applications) includes labeling for approximately 800 applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 505(b)) or section 351 of the Public Health Service Act (42 U.S.C. 262), 1,200 applications submitted under section 505(j) of the FD&C Act, and 2,000 revised drug product labeling from repackagers and relabelers for approximately 2,000 applications. This estimate also includes labeling amendments submitted to FDA for applications pending as of the effective date of the final rule. FDA estimates that it will take applicants approximately 40 hours to prepare and submit the subject labeling. This estimate applies only to the requirements of the final rule and does not indicate the total hours required to prepare and submit complete labeling for these applications. The information collection burden to prepare and submit labeling in accordance with §§ 201.56 (21 CFR 201.56), 201.57, and 201.80 is approved by OMB under control numbers 0910–0572 and 0910–0001.

In addition, during the 3rd, 4th, and 5th years after the effective date of the final rule, the Agency estimates that it will receive approximately 10,150 supplements to applications that were either approved from June 30, 2001, to the effective date or were pending as of the effective date. This estimate includes supplements for approximately 1,080 NDAs, BLAs, and efficacy supplements; 1,320 ANDA supplements; and 7,750 drug product labeling supplements from repackagers and relabelers. FDA estimates that approximately 390 application holders, repackagers, and relabelers will submit these supplements, and that it will take approximately 120 hours to prepare and submit each supplement.

FDA also estimates that application holders will submit approximately 5,500 annual reports to FDA during the third year after the effective date for applications that contain a pregnancy category, approved before June 30, 2001. This estimate includes approximately 1,340 NDAs and BLAs, and approximately 4,160 ANDAs containing labeling changes as a result of the final rule. FDA estimates that approximately 320 application holders will submit these annual reports, and that it will take approximately 40 hours for each submission.

Dated: September 28, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21292 Filed 10–3–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Patient Engagement Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; amendment.

SUMMARY: The Food and Drug Administration (FDA) is announcing amendments to the notice of meeting of the Patient Engagement Advisory Committee. This meeting was announced in the **Federal Register** of July 26, 2017. The amendments are being made to reflect time changes in the **DATES** and *Procedure* sections and to add *Webcast Information* to the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002, 301–796–8398; or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code PEAC. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 26, 2017 (82 FR 34681), FDA announced that a meeting of the Patient Engagement Advisory Committee would be held on October 11 and 12, 2017. On page 34681, in the third column, the **DATES** section is changed to reflect the time of these meetings on the announced dates.

On page 34682, in the first column, in the *Procedure* section, the third sentence is changed to reflect new times for oral presentations on October 11 and 12.

On page 34682, in the second column, a *Webcast Information* section is added before the last paragraph of the document. The amendments read as follows:

DATES: The meeting will be held on October 11, 2017, from 12:30 p.m. to 6 p.m. and October 12, 2017, from 8 a.m. to 5 p.m.

Procedure: Oral presentations from the public will be scheduled between approximately 2:30 p.m. to 3 p.m. on October 11, 2017, and approximately 1 p.m. to 2:30 p.m. on October 12, 2017.

Webcast Information: This meeting will also be made available to the public via webcast. The links for the webcasts are below: October 11, 2017: ''Patient Engagement Advisory Committee Meeting, Day 1,'' *https://event.webcasts.com/starthere.jsp?ei=1157277&tp_key=5580d0c7a5.* October 12, 2017: ''Patient Engagement Advisory Committee Meeting, Day 2,'' Morning Session—*https://event.webcasts.com/starthere.jsp?ei=1157280&tp_key=dfcde848fe;* and Afternoon Session—*https://event.webcasts.com/starthere.jsp?ei=1157282&tp_key=6d832a247e.*

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: September 29, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21317 Filed 10–3–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Azza El-Remessy, Ph.D., University of Georgia, College of Pharmacy: Based on the report of an investigation conducted by the University of Georgia, College of Pharmacy (UGCP) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Azza El-Remessy, former Associate Professor, Department of Clinical and Administrative Pharmacy, UGCP, engaged in research misconduct in research supported by National Eye Institute (NEI), National Institutes of Health (NIH), grants R01 EY011766, R01 EY022408, and R01 EY04618, National Heart, Lung, and Blood Institute (NHLBI), NIH, grant R01 HL056259, and National Cancer Institute (NCI), NIH, grant K01 CA89689.

ORI found that false Western blot data were included in:

- *J Cell Sci.* 118(Pt. 1):243–52, 2005 (hereafter referred to as ''*J Cell Sci.* 2005''). Retraction in: *J Cell Sci.* 129(16):3203, 2016.
- *FASEB J.* 21(10):2528–39, 2007 (hereafter referred to as ''*FASEB J.* 2007''). Retraction in: *FASEB J.* 31(1):421, 2017.
- *PLoS One* 8(8):e71868, 2013 (hereafter referred to as ''*PLoS One* 2013'').

As a result of its investigation, UGCP recommended that *PLoS One* 2013 be corrected. As a result of the investigation, *J Cell Sci.* 2005 and *FASEB J.* 2007 have been retracted.

ORI found that Respondent intentionally, knowingly, or recklessly used the same Western blot bands to represent different experimental results. Specifically, Respondent reused and relabeled bands in:

1. Figure 3B, *J Cell Sci.* 2005, to represent p38 bands from retinal cultured endothelial cells in high glucose in the absence of exogenous VEGF and also cells in peroxynitrite in the presence of exogenous VEGF.

2. Figure 4A, *J Cell Sci.* 2005, to represent nitrotyrosine immunoprecipitations from retinal endothelial cells cultured in normal glucose in the presence or absence of FeTTP; the Respondent also duplicated controls for p85 immunoprecipitation by using three bands representing 2 normal glucose and 1 high glucose treatments, flipping them horizontally (mirror images) to also represent 2 high glucose and 1 peroxynitrite treatments.

3. Figure 4B, *J Cell Sci.* 2005, to represent p85 immunoprecipitations from retinal endothelial cells stimulated with VEGF and also cells treated with either high glucose or peroxynitrite.

4. Figure 4A, *PLoS One* 2013, to represent immunoprecipitations for phosphorylated GSK-3 (p-GSK-3) in cells with normal glucose or high glucose for day 1 and to also represent cells treated with VEGF or VEGF+VEGFI (inhibitor); the Respondent also duplicated GSK-3 controls by using the same bands to represent high glucose treatment for day 1 and day 3 treatments, flipping them horizontally, to also represent for VEGF and VEGFRI treatments.

5. Figure 3, *FASEB J.* 2007, to represent phosphorylated VEGF2 (P-VEGF2) protein expression in microvascular endothelial cells in: Lanes 1 and 8, lanes 2 and 5, and lanes 6 and 7, where each lane represents different experimental conditions.

Dr. El-Remessy entered into a Voluntary Settlement Agreement (Agreement) to resolve this matter without further expenditure of time or other resources. Dr. El-Remessy accepts ORI's findings of research misconduct as set forth above but neither admits nor denies ORI's findings of research misconduct. The settlement is not an admission of liability on the part of the Respondent. Dr. El-Remessy voluntarily agreed, beginning on September 12, 2017:

(1) To have her research supervised for a period of three (3) years beginning with the effective date of the Agreement; Respondent agreed that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that for three (3) years beginning with the effective date of the Agreement,