[FR Doc. 2018–09430 Filed 5–3–18; 8:45 a.m.]
BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1707–N]

Medicare Program: Announcement of the Advisory Panel on Hospital Outpatient Payment (the Panel) Meeting on August 20–21, 2018

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (DHHS).

ACTION: Notice.

SUMMARY: This notice announces the annual meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) for 2018. The purpose of the Panel is to advise the Secretary of Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services concerning the clinical integrity of the Ambulatory Payment Classification groups and their associated weights as well as hospital outpatient therapeutic services supervision issues. The advice provided by the Panel will be considered as we prepare the annual updates for the hospital outpatient prospective payment system.

DATES:

Meeting Dates: Monday, August 20, 2018, 9:30 a.m. to 5 p.m. EDT through Tuesday, August 21, 2018, 9:30 a.m. to 1 p.m. EDT.

The times listed in this notice are Eastern Daylight Time (EDT) and are approximate times. Consequently, the meetings may last longer or be shorter than the times listed in this notice, but will not begin before the posted times:

Meeting Information Updates: The actual meeting hours and days will be posted in the agenda. As information and updates regarding the onsite, webcast, and teleconference meeting and the agenda become available, they will be posted to our website at: *http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.*

Deadline for Presentations and Comments: Presentations or comments and form CMS–20017, (located at *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms20017.pdf*) must be received by 5 p.m. EDT, Monday, July 23, 2018. Presentations and comments that are not received by the due date and time will be considered late and will not be included on the agenda. In commenting, refer to file code CMS–1707–N.

Meeting Registration Timeframe: Monday, June 25, 2018, through Monday, July 30, 2018 at 5 p.m. EDT.

Participants planning to attend this meeting in person must register online, during the specified timeframe at: *https://www.cms.gov/apps/events/default.asp.* On this web page, double click the ''Upcoming Events'' hyperlink, and then double click the ''HOP Panel'' event title link and enter the required information. Include any requests for special accommodations.

Note: Participants who do not plan to attend the meeting in person should not register. No registration is required for participants who plan to participate in the meeting via webcast or teleconference.

Because of staff and resource limitations, we cannot accept comments and presentations by facsimile (FAX) transmission.

Deadline for Requesting Special Accommodations: Monday, July 30, 2018 at 5 p.m. EDT.

ADDRESSES:

Meeting Location, Webcast, and Teleconference.

The meeting will be held in the Auditorium at the CMS Single Site campus, 7500 Security Boulevard, Baltimore, MD 21244. Alternately, the public may either view this meeting via a webcast or listen by teleconference. During the scheduled meeting, webcasting is accessible online at: *http://cms.gov/live.* Teleconference dial-in information will appear on the final meeting agenda, which will be posted on our website when available at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.*

News Media. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

Advisory Committees' Information Lines. The phone number for the CMS Federal Advisory Committee Hotline is (410) 786–3985.

Websites. For additional information on the Panel, including the Panel charter, and updates to the Panel's activities, we refer readers to view our website at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.*

Information about the Panel and its membership in the Federal Advisory Committee Act database are also located at: *http://facadatabase.gov/.*

Registration: The meeting is open to the public; but attendance is limited to the space available and registration is required. Priority will be given to those who pre-register and attendance may be limited based on the number of registrants and the space available.

Persons wishing to attend this meeting, which is located on federal property, must register by following the instructions in the **DATES** section of this notice under ''Meeting Registration Timeframe''. A confirmation email will be sent to the registrants shortly after completing the registration process.

FOR FURTHER INFORMATION CONTACT: Elise Barringer, Designated Federal Official (DFO), 410–786–9222, email at *APCPanel@cms.hhs.gov.* Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop: C4–04–25, Baltimore, MD 21244–1850.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Department of Health and Human Services (DHHS) is required by section 1833(t)(9)(A) of the Social Security Act (the Act) and is allowed by section 222 of the Public Health Service Act (PHS Act) to consult with an expert outside panel, such as the Advisory Panel on Hospital Outpatient Payment (the Panel), regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights. The Panel is governed by the provisions of the Federal Advisory Committee Act (Pub. L. 92–463), as amended (5 U.S.C. Appendix 2), to set forth standards for the formation and use of advisory panels. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the Hospital Outpatient Prospective Payment System (OPPS) for the following calendar year.

II. Meeting Agenda

The agenda for the August 20 through August 21, 2018 Panel meeting will provide for discussion and comment on the following topics as designated in the Panel's Charter:

- Addressing whether procedures within an APC group are similar both clinically and in terms of resource use.
- Evaluating APC group structure.
- Reviewing the packaging of OPPS services and costs, including the methodology and the impact on APC groups and payment.
- Removing procedures from the inpatient-only list for payment under the OPPS.
- Using single and multiple procedure claims data for Center for Medicare & Medicaid's (CMS') determination of APC group weights.

• Addressing other technical issues concerning APC group structure.

• Recommending the appropriate supervision level (general, direct, or personal) for individual hospital outpatient therapeutic services.

The Agenda will be posted on our website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html* approximately 1 week before the meeting.

III. Presentations

The subject matter of any presentation and comment matter must be within the scope of the Panel designated in the Charter. Any presentations or comments outside of the scope of this Panel will be returned or requested for amendment. Unrelated topics include, but are not limited to, the conversion factor, charge compression, revisions to the cost report, pass-through payments, correct coding, new technology applications (including supporting information/documentation), provider payment adjustments, supervision of hospital outpatient diagnostic services, and the types of practitioners that are permitted to supervise hospital outpatient services. The Panel may not recommend that services be designated as nonsurgical extended duration therapeutic services.

The Panel may use data collected or developed by entities and organizations other than DHHS and CMS in conducting its review. We recommend organizations submit data for CMS staff and the Panel's review.

All presentations are limited to 5 minutes, regardless of the number of individuals or organizations represented by a single presentation. Presenters may use their 5 minutes to represent either 1 or more agenda items.

Section 508 Compliance

For this meeting, we are aiming to have all presentations and comments available on our website. Materials on our website must be Section 508 compliant to ensure access to federal employees and members of the public with and without disabilities. We encourage presenters and commenters to reference the guidance on making documents Section 508 compliant as they draft their submissions, and, whenever possible, to submit their presentations and comments in a 508 compliant form. Such guidance is available at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/Section508/508-Compliant-doc.html.* We will review presentations and comments for 508 compliance and place compliant materials on our website. As resources permit, we will also convert non-compliant submissions to 508 compliant forms and offer assistance to submitters who wish to make their submissions 508 compliant. All non-508 compliant presentations and comments will be shared with the public onsite and through the webcast and made available to the public upon request.

Those wishing to access such materials should contact the DFO (the DFO's address, email, and phone number are provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice).

In order to consider presentations and/or comments, we will need to receive the following:

1. *An email* copy of the presentation or comments sent to the DFO mailbox, *APCPanel@cms.hhs.gov* or, if unable to submit by email, a hard copy sent to the DFO at the address noted in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

2. Form *CMS–20017* with complete contact information that includes name, address, phone number, and email addresses for all presenters and commenters and a contact person that can answer any questions, and provide revisions that are requested, for the presentation. Presenters and commenters must clearly explain the actions that they are requesting CMS to take in the appropriate section of the form. A presenter's or commenter's relationship with the organization that they represent must also be clearly listed.

• The form is now available through the CMS Forms website at: *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms20017.pdf*.

• We encourage presenters to make efforts to ensure that their presentations and comments are 508 compliant.

IV. Oral Comments

In addition to formal oral presentations (limited to 5 minutes total per presentation), there will be an opportunity during the meeting for public oral comments (limited to 1 minute for each individual) and a total of 3 minutes per organization.

V. Panel Recommendations and Discussions

The Panel's recommendations at any Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day of the meeting, before the final adjournment. These recommendations will be posted to our website after the meeting.

VI. Security, Building, and Parking Guidelines

The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting the DFO at the address listed in the **ADDRESSES** section of this notice or by telephone at the number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

• Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.

• Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.

• Inspection, via metal detector or other applicable means of all persons brought entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

VII. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: April 23, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–09532 Filed 5–3–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–N–0075; FDA–2011–N–0015; FDA–2011–N–0076; FDA–2017–N–0932; FDA–2016–N–4487; FDA–2014–N–0345; FDA–2013–N–0523; FDA–2017–N–2428; FDA–2008–N–0312; and FDA–2014–N–1072]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals'' that appeared in the **Federal Register** of April 9, 2018. The document announced a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, April 9, 2018 (83 FR 15152), in FR Doc. 2018–07147, on page 15152, the following correction is made:

1. On page 15152, in the second column, in the first line of the list of docket numbers, ''FDA–2014–N–0075'' is corrected to read ''FDA–2011–N–0075.''

Dated: April 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–09437 Filed 5–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1534]

Sun Pharmaceutical Industries, Ltd.; Withdrawal of Approval of Three Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of three abbreviated new drug applications (ANDAs) held by Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc. (Sun Pharmaceutical). These drug products are no longer marketed, and Sun Pharmaceutical has requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 4, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Sun Pharmaceutical has informed FDA that these drug products are no longer marketed and requested that FDA withdraw approval of the applications. Sun Pharmaceutical has also waived its opportunity for a hearing and requested withdrawal of approval under a Consent Decree of Permanent Injunction (Decree) entered in *United States* v. *Ranbaxy Laboratories, Ltd. et al.,* JFM 12–250 (D. Md.) on January 26, 2012. The Decree specifies that Sun Pharmaceutical must never submit another application to FDA for these withdrawn drugs and must never transfer these ANDAs to a third party.

Application No.	Drug	Applicant
ANDA 065174	Clarithromycin Tablets USP, 250 milligrams (mg) and 500 mg.	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 065382	Clarithromycin for Oral Suspension USP, 125 mg/5 milliliters (mL) and 250 mg/5 mL.	Do.
ANDA 075747	Ciprofloxacin Tablets USP, Equivalent to (EQ) 250 mg base, EQ 500 mg base, and EQ 750 mg base.	Do.

Therefore, approval of the applications listed in the above table, and all amendments and supplements thereto, is hereby withdrawn as of June 4, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)).

Dated: May 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–09533 Filed 5–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1564]

Ferndale Laboratories, Inc., et al.; Withdrawal of Approval of Nine Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of nine abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 4, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and