Food and Drug Administration
Center for Drug Evaluation and Research

Summary Minutes of the Meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee
September 20, 2018

Location: FDA White Oak Campus, 10903 New Hampshire Avenue, Building 31 Conference Center, The Great Room (Rm. 1503), Silver Spring, Maryland

Topic: The meeting focused on two topics related to the Office of Pharmaceutical Quality's priority of promoting the availability of better medicine. During the morning session, the committee discussed the modernization of assessing drug applications through a Knowledge-aided Assessment and Structured Application (KASA) initiative. FDA sought input on the potential enhancement of submission format consistent with KASA to improve the efficiency and consistency of regulatory quality assessment. During the afternoon session, the committee discussed in-vitro in-vivo relationship (IVIVR) standards, and sought input on establishing patient-focused dissolution standards for oral solid modified-release dosage forms.

These summary minutes for the September 20, 2018, meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee of the Food and Drug Administration were approved on November 8, 2018.

I certify that I attended the September 20, 2018, meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/
Jennifer Shepherd, RPh
Acting Designated Federal Officer, PSCP

/s/
Gregory E. Amidon, PhD
Chairperson, PSCP

Summary Minutes
Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting
September 20, 2018

The Pharmaceutical Science and Clinical Pharmacology Advisory Committee (PSCP) of the Food and Drug Administration, Center for Drug Evaluation and Research, met on September 20, 2018, at the FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503), 10903 New Hampshire Avenue, Silver Spring, Maryland. Prior to the meeting, the members and temporary voting members were provided the briefing materials from the FDA. The meeting was called to order by Gregory E. Amidon, PhD (Chairperson). The conflict of interest statement was read into the record by Jennifer Shepherd, RPh (Acting Designated Federal Officer). There were approximately 50 people in attendance. There were no Open Public Hearing (OPH) speaker presentations in the morning session or afternoon session.

A verbatim transcript will be available, in most instances, at approximately ten to twelve weeks following the meeting date.

Agenda: The meeting focused on two topics related to the Office of Pharmaceutical Quality's priority of promoting the availability of better medicine. During the morning session, the committee discussed the modernization of assessing drug applications through a Knowledge-aided Assessment and Structured Application (KASA) initiative. FDA sought input on the potential enhancement of submission format consistent with KASA to improve the efficiency and consistency of regulatory quality assessment. During the afternoon session, the committee discussed in-vitro in-vivo relationship (IVIVR) standards, and sought input on establishing patient-focused dissolution standards for oral solid modified-release dosage forms.

Attendance:

Pharmaceutical Science and Clinical Pharmacology Advisory Committee Members Present (Voting): Gregory E. Amidon, PhD (Chairperson/Pharmaceutical Sciences); Jeffery M. Carrico, PharmD, BCPS; Sandra Finestone, PsyD (Consumer Representative); Tonglei Li, PhD; Donald E. Mager, PharmD, PhD; Patricia W. Slattum, PharmD, PhD, GCP; Duxin Sun, PhD; Andre Terzic, MD, PhD, FAHA

Pharmaceutical Science and Clinical Pharmacology Advisory Committee Members Not Present (Voting): Scott A. Waldman, MD, PhD (Chairperson/Clinical Pharmacology)

Pharmaceutical Science and Clinical Pharmacology Advisory Committee Members Present (Non-Voting): Walid Awni, PhD (Industry Representative); Jack A. Cook, PhD (Industry Representative); Srini Tenjarla, PhD (Industry Representative)

Temporary Members (Voting): Maureen D. Donovan, PhD; James E. Polli, PhD (*Afternoon Session Only*); Paul J. Smith, PhD, MS

FDA Participants (Non-Voting): Michael Kopcha, PhD, RPh, Lawrence X. Yu, PhD; Susan M. Rosencrance, PhD (*Morning Session Only*)

Designated Federal Officer (Non-Voting): Jennifer Shepherd, RPh

Open Public Hearing Speakers: Morning Session - None; Afternoon Session - None

The agenda was as follows:

Call to Order and Introduction of Committee	**Gregory E. Amidon, PhD** Chairperson, PSCP
Conflict of Interest Statement	**Jennifer Shepherd, RPh** Acting Designated Federal Officer, PSCP
FDA Introductory Remarks	**Michael Kopcha, PhD, RPh** Director Office of Pharmaceutical Quality (OPQ) CDER, FDA

KNOWLEDGE-AIDED ASSESSMENT AND STRUCTURED APPLICATION (KASA)

FDA PRESENTATIONS

Introduction	**Susan M. Rosencrance, PhD** Director Office of Lifecycle Drug Products (OLDP) OPQ, CDER, FDA
Product Risk Assessment and Mitigation	**Andre Raw, PhD** Acting Senior Scientific and Policy Advisor OLDP, OPQ, CDER, FDA
Manufacturing Risk Assessment and Mitigation	**Christina Capacci-Daniel, PhD** Acting Quality Assessment Lead Office of Process and Facilities OPQ, CDER, FDA
Structure Application and Benefits of KASA	**Larisa C. Wu, PhD** Special Assistant, Chemist OPQ, CDER, FDA

Clarifying Questions

BREAK

OPEN PUBLIC HEARING

Questions to the Committee/Committee Discussion

LUNCH

PATIENT FOCUSED QUALITY STANDARDS FOR EXTENDED-RELEASE SOLID ORAL PRODUCTS; IN VITRO AND IN VIVO RELATIONSHIPS

Conflict of Interest Statement	**Jennifer Shepherd, RPh** Acting Designated Federal Officer, PSCP

FDA PRESENTATIONS

Patient Focused Quality (Dissolution) Standards for High Solubility Drugs and Advances in Predictive Dissolution Technology	**Richard Lostritto, PhD** Associate Director for Science Office of Policy for Pharmaceutical Quality (OPPQ), OPQ, CDER, FDA
Establishing the *In Vitro-In Vivo* Link for Pharmaceutical Manufacturing and Quality	**Paul Seo, PhD** Director Division of Biopharmaceutics (DP) Office of New Drug Products (ONDP) OPQ, CDER, FDA
Understanding Bioperformance Risk for Extended-Release Oral Drug Products	**Lawrence X. Yu, PhD** Deputy Director OPQ, CDER, FDA

Clarifying Questions

BREAK

OPEN PUBLIC HEARING

Questions to the Committee/Committee Discussion

ADJOURNMENT

Questions to the Committee:

Morning Session:

1. **VOTE:** Relating to the KASA initiative, should the FDA consider the enhancement of submission format to improve the efficiency and consistency of regulatory quality assessment?

   Vote Result: ***YES: 10*** ***NO: 0*** ***ABSTAIN: 0***

   Committee Discussion: *The committee unanimously agreed that, relating to the KASA initiative, the FDA should consider enhancement of submission format to improve the efficiency and consistency of regulatory quality assessment under the KASA initiative. Several members stated that this would increase communication while making submissions from industry easier and more transparent. Brand and generic industry representatives on the committee also agreed that KASA would be good for industry and FDA. Members encouraged a flexible design, so data is searchable, easily transposable and exportable for further analysis. Please see the transcript for details of the Committee discussion.*

Afternoon Session:

1. **VOTE:** Should the FDA establish patient-focused dissolution standards for extended-release solid oral dosage forms?

   Vote Result: ***YES: 11*** ***NO: 0*** ***ABSTAIN: 0***

   Committee Discussion: *The committee unanimously agreed that the FDA should establish patient-focused dissolution standards for extended-release solid oral dosage forms. There was significant discussion of the best semantics to describe the approach but universal agreement that patient focused standards represented a better approach and that advances in IVIVR modelling and predictive dissolution made such an approach viable. Several members agreed that this would advance pharmaceutical science, improve drug and quality standards, and increase our understanding of extended-release dosage forms. A member stated– and other agreed – that FDA should consider the same approach for BCS class II IR dosage forms.Please see the transcript for details of the Committee discussion*

The meeting was adjourned at approximately 3:33 p.m.