

**2020 – 2025 Biologics Monographs 1 – Peptides and Oligonucleotides Expert Committee
(BIO1 EC)**

**Thursday, March 4, 2021
9:00 AM - 10:00 A.M.**

**Teleconference
Agenda - Draft**

Goals and Anticipated Outcomes

- Teriparatide Revisions in the Coming Ballot
- Review Public Comments of Glucagon Monograph Revision
- Discuss General Chapters of Oligonucleotides

Attendees

Expert Committee Members

- | | |
|--------------------------------|-----------------------|
| 1. Michael De Felippis (Chair) | 8. Ved Srivastava |
| 2. Gerhard Haas (Vice Chair) | 9. Jessica Stolee |
| 3. Ben Cowper | 10. Michael Verlander |
| 4. Marc Lemaitre | 11. Marc Wiles |
| 5. Yi Hong Lu | 12. Allison Wolf |
| 6. Antonio Ricci | 13. Dongyue Xin |
| 7. Raimon Rubires | |

Government Liaisons

Donna Christner, FDA; Cory Evans, FDA; Anjali Shukla, FDA

Observer

Xia Bai, FDA

USP Staff

Sarita Acharya, Alice Akinsulie, Shy Bhattacharya, Kevin Carrick, Li Jing, Diane McCarthy, Manoj Metta, Doug Podolsky, Dale Schmidt, Julie Zhang

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| 9:00 a.m. | 1. Opening, Procedural, and Administrative Matters | |
| | a. Welcome, Opening Remarks, Introduction | Dr. De Felippis |
| | b. Roll Call, Establish Quorum | Ms. Akinsulie |
| | c. Conflicts of Interest, Confidentiality, Code of Ethics and Recording Policy | Ms. Akinsulie |
| | d. Approval of Agenda | Dr. De Felippis |
| | e. Approval of Previous Minutes | Dr. De Felippis |
| | f. Review of Action Items | Dr. Zhang |
| 9:15 a.m. | 2. Teriparatide Revisions | |
| | a. Review Teriparatide Revisions | Dr. Zhang |
| | b. Discussion | All |

**CLOSED TO CONFLICTED MEMBERS, GOVERNMENT LIAISONS,
OBSERVERS, INVITED GUESTS, AND ALL STAFF WITH
EXCEPTION OF THE ECM**



- c. Final Discussion Non-conflicted EC members
- d. Vote on Advancing an Item(s) for Final Balloting Non-conflicted EC members

END CLOSED SESSION

- e. Summary of Decision Made During Final Discussion Dr. De Felippis

- 9:25 a.m. **3. Glucagon Public Comments**
 - a. Review Public Comments and Proposed Revisions Dr. Zhang
 - b. Discussion All
 - c. Agree to Publish to PF All

- 9:40 a.m. **4. Propose for Initiating General Chapters for Oligonucleotides**
 - a. Proposed General Chapters for Oligonucleotides TBD
 - b. Discussion on Priority All

- 9:55 a.m. **4. Meeting Wrap-up and Action Items**
 - a. Action Items Ms. Akinsulie
 - b. Scheduling/Reminder of Next Meeting Ms. Akinsulie

- 10:00 a.m. **Adjourn**