

General Chapters Dosage Forms Expert Committee (GCDF) Monday, April 5, 2021 9:00a.m.-11:00 a.m. Teleconference

Agenda - Draft

Goals and Anticipated Outcomes

• To approve items for ballot and discuss the ongoing projects of subgroups.

Attendees

• Attendee list to be provided the day of the meeting

9:00 a.m.	1.	Opening,	Procedural.	and	Administrative Matters
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a.	Welcome, Opening Remarks, Introduction	Dr. Coffey
b.	Roll Call	Ms. von Berg
C.	Establish quorum	All
d.	Conflicts of Interest, Confidentiality, Code of Ethics and	Ms. von Berg
	Recording Policy	
e.	Approval of Agenda	Dr. Coffey
f.	Approval of Minutes of Previous Meeting (December 4,	Dr. Coffey
	2020)	

9:15 a.m. **2. Approval of Chapters and Reference Standards for Balloting**

Decision Making

a. Reference Standard Ballot (Ballot dates April 12-April 18)

i. Prednisone Tablet RSCEP Review	Drs. MacDonald,
	Liddell, Mr. Walfish
ii. Call for Recusal for Conflicted Members	Dr. Coffey
iii. Discussion for any items warranting EC decision	Non-conflicted EC
making	members
iv. Motion – Moving Reference Standard to Ballot	Non-conflicted EC
	members

b. Chapter Ballots (Ballot dates June 25-July 4)

i. <711> Dissolution	Dr. Marques
ii. <1001> In Vitro Release Test Methods For	Dr. Hunt
Parenteral Drug Preparations	
iii. <1212> Probe Tack Test	Dr. Marques
iv. <1790> Visual Inspection Of Injections	Dr. Hunt
v. Call for Recusal for Conflicted Members	Dr. Coffey

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vi. Discussion for any items warranting EC decision making

vii. Motion – Moving Chapters to Ballot

Non-conflicted EC members Non-conflicted EC members

Mses. Hammann, Jobe

Dr. Hunt

Dr. Zaidi

Ms. Furr

Dr. Marques

Dr. Marques

Dr. Marques

Dr. Reddy-Gruddanti

10:30 a.m. 3. Expert Committee Sub-group Activities

c. Balloting Process

Informational/Discussion

a. <788> Particulate Matter in Injections Expert Panel

b. New Advancements in Product Performance Testing Expert Panel

c. Performance Test for Semisolid Dosage Forms Expert Panel

d. <1151> Pharmaceutical Dosage Forms Subcommittee

e. Inhalation Dosage Forms Subcommittee

i. 134a Monograph

ii. Inhalation and Nasal Drug Products—General Information and Product Quality Tests <5>

iii. Presentation Of Aerodynamic Particle Size Distribution Measurement Data <1604>

f. Medical Devices Joint Subcommittee

g. Brief Subgroup/Chapter updates

i.<771> Opthalmic Products – Quality Tests

• Publication in PF 47(3), deadline for comments is July 31, 2021.

10:50 a.m. 4. Meeting Wrap-up and Action Items

a. Action items

b. Scheduling/Timing of next meeting

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