<1059> Excipient Performance

Type of Posting: Notice of Intent to Revise
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Expert Committee Excipient Monographs 1 Expert Committee

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Excipient Monographs 1 Expert Committee intends to revise general chapter <1059> *Excipient Performance*.The purpose of the proposed revision is:

- Addition of missing NF functional categories to <1059> and to the USP reference table *USP and NF Excipients, Listed by Functional Category* to include excipients used in specialized dosage forms according to General Chapter <1151> *Pharmaceutical Dosage Forms* (for example biologics and injectables)
- Alignment of types of dosage forms listed in the Dosage Forms section of each functional category with those described in ?1151?
- Revision of the existing functional categories to update any outdated or missing information

The specific proposed revisions are as follows:

- Change the chapter layout. Because one functional category can be used in multiple dosage forms, remove the dosage form titles under which the functional categories were grouped. Under each functional category create a section titled *Dosage Forms* that contains a list of dosage forms in which the functional category is generally used.
- Divide the *pH Modifier (Acidifying/Alkalizing/Buffering Agent)* functional category into two functional categories, *Acidifying and Alkalizing Agent* and *Buffering Agent*, respectively.
- Revise the category title *Adhesive* to *Adhesive (Pressure Sensitive)*.
- Combine the *Capsule Shell* and *DPI Capsule Shell* categories under *Capsule Shell*.
- Add 29 new NF functional categories

It is anticipated that the proposed revision posted below will be published as an In Process Revision (IPR) in *Pharmacopeial Forum* 46(1) [Jan.–Feb. 2020] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on March 31, 2020. In the absence of any adverse comments the proposed IPR will become official on May 1, 2021.

Please click here to download the revision proposal.

Should you have any questions, please contact Galina Holloway, Scientific Liaison to the Excipient Monographs 1 Expert Committee (301–816–8133 or gvh@usp.org).

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