GENERAL NOTICES PROJECT TEAM UPDATES

CHUCK BATES,
OCTOBER 24, 2019
AGENDA

- General Notices Background
- Section 5.80. USP Reference Standards
- Global Health Monographs
- Section 5.20 Added Substances and Section 5.60 Impurities and Foreign Substances
- What’s coming up…
WHO WE ARE...GENERAL NOTICES

CHARLES (CHUCK) BATES, CHAIR, MWCDG

• Stephanie Ajaj, (MWCDG)
• Joseph A. Albanese, (PhRMA)
• Sue Beavis, (CHPA)
• Chung Chow Chan, (CVG)
• George Collins Jr., (IPEC-A)
• Hong Du, (AAM)
• Lisa Eichler, (MWCDG)

• Gina Marsee, (PDA)
• Hantz Tattegrain, (NJPQCA)
• Janeen Skutnik-Wilkinson, (PDA)
• Pallavi Nithyanandan, (FDA)
• Priscilla Zawislak, (IPEC, Federation)
• Saji Thomas, (AAPS)
• Yan-Bo Yang, (WCDG)
• Catherine Vicente, (IPEC-A)
GENERAL NOTICES

SECTION 5.80. USP REFERENCE STANDARDS

• Was already in process when group formed
• Ongoing revisions, received one comment on for General Notices in conjunction with General Chapter 〈11〉 USP Reference Standards during the comment period.
• In review with the Expert Committee
• Aiming for USP 43, Supplement 1
GLOBAL HEALTH MONOGRAPHS

• Issue was to move Global Health Monograph in a different section to avoid confusion for stakeholders.
• Proposed language 3.10.40 Applicability of Global Health Monographs
• Elevating Global Health Monographs from Front Matter to the General Notices in a prominent area to increase visibility and understanding
• Council of Experts have discussed, targeting PF 46(1)
GENERAL NOTICES

SECTION 5.20 ADDED SUBSTANCES AND SECTION 5.60 IMPURITIES AND FOREIGN SUBSTANCES

- Trying to determine verbiage that can be added so that the proprietary information from excipients is not exposed
- Discussion ongoing awaiting suggested language
What’s Coming Up…

• Current discussion just started regarding issues arising from Stability Specifications requirements in Climatic Zones outside the USA
Thank You