Appendix D

Selected Websites Pertaining to Compounding Sterile Preparations

Accreditation Commission for Health Care (ACHC and PCAB)

- ACHC pharmacy accreditation services. www.achc.org/programs/pharmacy (accessed 2017 Jan 3).

American Osteopathic Association—Healthcare Facilities Accreditation Program (HFAP)

- Accreditation requirements for acute care hospitals: pharmacy services/medication use. www.hfap.org/pdf/ManualUpdates/250110.pdf (accessed 2017 Jan 4).

American Society for Parenteral and Enteral Nutrition (ASPEN)

- Boullata JI, Gilbert K, Sacks G et al. Clinical guidelines: parenteral nutrition ordering, order review, compounding, labeling, and dispensing. www.journals.sagepub.com/doi/abs/10.1177/0148607114521833 (accessed 2017 Jan 3).
- Ayers P, Adams S, Boullata J et al. ASPEN parenteral nutrition safety consensus recommendations. *JPEN*. 2014; 38:296-333.

Controlled Environment Testing Association International (CETA)

- Application guides. www.cetainternational.org/ceta-application-guides-for-nonmembers- (accessed 2017 Jan 3).

Department of Health and Human Services, Office of Inspector General

- Medicare's oversight of compounded pharmaceuticals used in hospitals. Report (OEI-01-13-00400). www.oig.hhs.gov/oei/reports/oei-01-13-00400.asp (accessed 2017 Jan 3).

Environmental Protection Agency (EPA)

- Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. www.epa.gov/rcra/resource-conservation-and-recovery-act-rcra-regulations (accessed 2017 Jan 3).

Institute for Safe Medication Practices (ISMP)

- 2016–2017 targeted medication safety best practices for hospitals. www.ismp.org/tools/bestpractices/TMSBP-for-Hospitals.pdf (accessed 2017 Jan 3).
- Proceedings from the ISMP sterile preparation compounding safety summit: guidelines for SAFE preparation of sterile compounds, 2013. www.ismp.org/tools/guidelines/IVSummit/IVCGuidelines.pdf (accessed 2017 Jan 3).

Institute of Environmental Sciences and Technology (IEST)

- IEST-RP-CC012: considerations in cleanroom design. www.iest.org/Standards-RPs/Recommended-Practices/IEST-RP-CC012 (accessed 2017 Jan 3).

International Standards Organization (ISO)

- Cleanrooms and associated controlled environments 14644. www.iso.org/standard/53394.html (accessed 2017 Jan 4).

National Association of Boards of Pharmacy (NABP)

- The Model State Pharmacy Act and model rules of the National Association of Boards of Pharmacy—August 2016. www.nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/ (accessed 2017 Jan 3).

National Institute for Occupational Safety and Health (NIOSH)

- Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. www.cdc.gov/niosh/docs/2004-165/ (accessed 2017 Jan 3).

NSF International (NSF) and American National Standards Institute (ANSI)

- NSF/ANSI Standard 49—2011, biosafety cabinetry: design, construction, performance, and field certification. www.nsf.org (accessed 2017 Jan 3).

United Credentialing and Accreditation Program

- Accreditation program for compounding pharmacies. www.focusscript.com/pharmacy-locator/#locator-table (accessed 2017 Jan 3).

United States 113th Congress, First Session 2013

- Drug Quality and Security Act of 2013 title 1. www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm#Section (accessed 2017 Jul 16).

U.S. Food and Drug Administration (FDA)

503A-related links

- Hospital and health system compounding under the Federal Food, Drug, and Cosmetic Act guidance for industry (draft guidance 2016 Apr). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496287.pdf (accessed 2017 Jan 4).
- Section 503A of the Federal Food, Drug, and Cosmetic Act. www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376733.htm (accessed 2017 Jan 3).

503A- and 503B-related links

- Unsanitary conditions at compounding facilities guidance for industry (draft guidance 2016 Aug). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM514666.pdf (accessed 2016 Jan 4).
- Repackaging of certain human drug products by pharmacies and outsourcing facilities (final guidance 2017 Jan). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf (accessed 2017 Jul 16).
- FDA's human drug compounding progress report (2017 Jan). www.fda.gov/downloads/drugs/guidance complianceregulatoryinformation/pharmacycompounding/ucm536549.pdf (accessed 2017 Jul 16).

503B-related links

- Adverse event reporting for outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (final guidance 2015 Oct). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434188.pdf (accessed 2017 Jan 4).

- Compounded drug products that are essentially copies of approved drug products under section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (draft guidance 2016 Jul). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510153.pdf (accessed 2017 Jan 4).
- Current good manufacturing practice—interim guidance for human drug compounding outsourcing facilities under section 503B of the FD&C Act (draft guidance 2014 Jul). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM403496.pdf (accessed 2017 Jan 4).
- Facility definition under section 503B of the Federal Food, Drug, and Cosmetic Act (draft guidance 2016 Apr). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496288.pdf (accessed 2017 Jan 4).
- Interim policy on compounding using bulk drug substances under section 503B of the Federal Food, Drug, and Cosmetic Act (revised final guidance 2017 Jan). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf (accessed 2017 Jul 16).
- Outsourcing facilities (section 503B). www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm393571.htm (accessed 2017 Jul 16).
- Registration for human drug compounding outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (final guidance 2014 Nov). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377051.pdf (accessed 2017 Jan 4).

Other links

- Compounded drug products that are essentially copies of a commercially available drug product under section 503A of the Federal Food, Drug, and Cosmetic Act guidance for industry (draft guidance 2016 Jul). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510154.pdf (accessed 2017 Jan 4).
- Form letter from Margaret A. Hamburg, MD, Commissioner of Food and Drugs, to hospital pharmacists (2014 Jan 8). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM380599.pdf (accessed 2017 Jan 3).
- Interim policy on compounding using bulk drug substances under section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (revised final guidance 2017 Jan). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf (accessed 2017 Jul 16).
- Pharmacy compounding of human drug products under section 503A of the Federal Food, Drug and Cosmetic Act (final guidance 2016 Jun). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469119.pdf (accessed 2017 Jul 16).
- Prescription requirement under section 503A of the Federal Food, Drug, and Cosmetic Act (final guidance 2016 Dec). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf (accessed 2017 Jan 4).

United States Pharmacopoeia/National Formulary (*USP–NF*)

- U.S. Pharmacopeial Convention. USP chapter <797> pharmaceutical compounding—sterile preparations and USP chapter <800> hazardous drugs—handling in healthcare settings. www.usp.org/store/products/usp-compounding-compendium (accessed 2017 Jan 3).