

The Trials and Tribulations of Assuring Ascorbic Acid Injection Availability – The Struggle Is Over!

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References

1. Consent Decree of Condemnation and Permanent Injunction previously entered against Steris Laboratories, Inc.
<http://www.secinfo.com/ds4Px.715d.c.htm>
2. Guidance on Marketed Unapproved Drugs; Compliance Policy Guide.
<https://www.federalregister.gov/documents/2006/06/09/E6-9032/guidance-on-marketed-unapproved-drugs-compliance-policy-guide-availability>
3. Multistate Outbreak of Fungal Meningitis and Other Infections – Case Count.
<https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html>
4. FDA draft and final guidances on compounding pharmacy were published since July 1, 2014.
<https://www.fda.gov/drugs/guidancecompliance regulatory information/guidances/ucm452240.htm>
5. Drug Quality and Security Act. <https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf>
6. Draft Memorandum of Understanding. <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory Information/Pharmacy Compounding/UCM434233.pdf>
7. FDA Approved Drug Products.
<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209112>
8. Prescribing information and package insert.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209112s000lbl.pdf
9. Orphan Drug Designations and Approvals.
<https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=243707>
10. A Pharmacokinetics Study of Intravenous Ascorbic Acid.
<https://www.clinicaltrials.gov/ct2/show/NCT02534753?term=mcguff&rank=1>
11. For complete prescribing information for Ascor® (Ascorbic Acid Injection):
<http://www.mcguffpharmaceuticals.com/PDF/Ascor%20Package%20Insert.pdf>
12. Outsourcing facilities manufacture’s registration of drug products produced.
<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM577376.xlsx>