

Q&A Follows on page 6 – 8: Bulk Drug Substances for Pharmacy Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act – PS Anderson 09-2018 Confidential

Upon enactment of this process  
Cat-1 “yes” will be legal to  
compound and “no” illegal to  
compound; Cat-2 are  
immediately illegal; Cat-3 will all  
immediately be illegal to  
compound. – 310 substances  
total with 16 “approved” and 18  
left to be heard.

**Category-1**

FINDINGS TO DATE FROM THE 503  
HEARINGS (53 OF 68)

Yes:

- 1) Alpha Lipoic Acid (ORAL ONLY)
- 2) brilliant Blue G
- 3) cantharidin
- 4) Coenzyme Q10 (Oral)
- 5) Creatine, Monohydrate (Oral)
- 6) diphenylcyclopropanone
- 7) diphenylcyclopropanone (DPCP)( topical use)
- 8) DMPS
- 9) glutaraldehyde for topical use
- 10) glycolic acid for topical use
- 11) pyruvic acid for topical use
- 12) Pyridoxal 5-Phosphate Monohydrate (Oral or IV)
- 13) squaric acid dibutyl ester
- 14) tea tree oil
- 15) thymol iodine
- 16) trichloroacetic acid for topical use

No:

- 1) acetyl-L-carnitine
- 2) alanyl-L-glutamine
- 3) Aloe Vera freeze dried 200:1
- 4) artemisinin
- 5) boswellia
- 6) chondroitin sulfate for topical use
- 7) chrysin
- 8) curcumin
- 9) D-ribose
- 10) deoxy-D-glucose
- 11) dichloroacetate (DCA)

- 12) diindolylmethane
- 13) glycyrrhizin
- 14) kojic acid
- 15) methylsulfonylmethane (MSM)
- 16) nettle
- 17) N-acetyl-D-glucosamine
- 18) nicotinamide adenine dinucleotide (NAD)
- 19) nicotinamide adenine dinucleotide disodium (NADH)
- 20) oxitriptan (listed for denial in the 12/16/2016 NPRM)
- 21) piracetam (listed for denial in the 12/16/2016 NPRM)
- 22) Quercetin
- 23) quinacrine hydrochloride
- 24) rubidium chloride
- 25) silver protein mild
- 26) tranilast
- 27) ubiquinol
- 28) vanadyl sulfate
- 29) vasoactive intestinal peptide

Awaiting Hearings:

1. 7-Keto-DHEA
2. Acetyl Glucosamine
3. [“TM”] Ammonium Tetrathiomolybdate
4. Beta Glucan (1,3/1,4-D)
5. Bromelain
6. Capsaicin palmitate
7. Cetyl Myristoleate
8. Choline Chloride
9. EGCG
10. Ferric Subsulfate
11. Glutathione
12. Glycoaminoglycans
13. L-Citrulline
14. Methylcobalamin
15. Ornithine Hydrochloride
16. Phosphatidylserine
17. Pregnenolone
18. Resveratrol

**Category-2**

**NOTE: THESE ARE IMMEDIATELY**

**ILLEGAL TO COMPOUND**

**Updated May 1, 2017**

**503A Category 2: Bulk Drug**

**Substances that Raise “Significant Safety Risks”**

- 1. Cesium chloride**
- 2. Domperidone**
- 3. Quinacrine Hydrochloride  
for intrauterine  
administration**
- 4. Germanium Sesquioxide**

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**Category-3**

**NOTE: THESE ARE JUDGED NOT WORTHY OF A HEARING AND WILL BECOME ILLEGAL TO COMPOUND AUTOMATICALLY (255)**

**503A Category 3: Bulk Drug Substances Nominated Without Adequate Support**

- |   |   |
|---|---|
| 1. Acetanilide  | 41. Copper  |
| 2. Acidophilus Lactobacillus  | 42. Copper Bisglycinate                                 |
| 3. Adenosine-5-triphosphate disodium salt                           | 43. Copper Hydrosol                                     |
| 4. Alcloxa  | 44. Decylmethylsulfoxide                                |
| 5. Aldioxa  | 45. Diaminopyridine (3,4-)                              |
| 6. Aldosterone  | 46. Dichloroacetic acid                                 |
| 7. Alfalfa  | 47. Dimethyl Ketone                                     |
| 8. Alfalfa leaves   | 48. Dimethylaminoethanol Bitartrate                     |
| 9. Almadrate sulfate  | 49. Dimethylglycine Hydrochloride                       |
| 10. Aloin   | 50. Dinitrochlorobenzene                                |
| 11. Alpha Ketoglutaric acid   | 51. Disodium Phosphate                                  |
| 12. Alumina Powder, hydrated  | 52. Edetate tetrasodium tetrahydrate                    |
| 13. Aluminum phosphate  | 53. Gamma Aminobutyric Acid                             |
| 14. Aminacrine Hydrochloride  | 54. GHRP-2  |
| 15. Ammonium bromide  | 55. GHRP-6  |
| 16. Ammonium hydroxide  | 56. Ginger root powder                                  |
| 17. Anise seed  | 57. Ginkgo Biloba Standardized Extract                  |
| 18. Argentyn  | 58. Gluconic acid calcium salt                          |
| 19. Aromatic powder   | 59. Glycerol Formal                                     |
| 20. Asafetida   | 60. Glydiazinamide                                      |
| 21. Asclepias tuberosa  | 61. Grape seed oil                                      |
| 22. Asefetida Tincture  | 62. Heart-leaf nettle leaf (Urtica chamaedryoides leaf) |
| 23. Asparagus   | 63. Hyaluronic Acid Sodium Salt                         |
| 24. Aspergillus oryza enzymes                                       | 64. Hydrazine sulfate                                   |
| 25. Barosma   | 65. Indigo Carmine                                      |
| 26. Beechwood creosote  | 66. Indole-3-carbinol                                   |
| 27. Bean  | 67. Inositol Hexanicotinate                             |
| 28. Betamechlomathasone   | 68. Iron Glycinate Chelate                              |
| 29. Beta-Nicotinamide Adenine Dinucleotide Disodium Salt Trihydrate | 69. Karaya Gum  |
| 30. Bichloroacetic Acid   | 70. L-Carnosine   |
| 31. Calcium Folate  | 71. Levulose  |
| 32. Calcium Glycinate   | 72. L-Histidine Monohydrochloride, Monohydrate          |
| 33. Carbazochrome   | 73. L-Ornithin Hydrochloride                            |
| 34. Carbimazole   | 74. Magnesium ascorbate                                 |
| 35. Cedarwood Essential Oil   | 75. Magnesium bisglycinate                              |
| 36. Chlorhexidine Diacetate Hydrate                                 | 76. Magnesium bisglycinate dihydrate                    |
| 37. Choline bitartrate  | 77. Magnesium glycinate                                 |
| 38. Choline magnesium trisalicylate                                 | 78. Malt  |
| 39. Chromium glycinate  | 79. Malt soup extract                                   |
| 40. Coenzyme Q50  | 80. Maltodextrin  |
|   | 81. Manganese Bisglycinate                              |
|   | 82. Manganese citrate                                   |
|   | 83. m-cresol  |

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84. Melatonin	127. Ox bile
85. Menfegol	128. Ox bile extract
86. Meralein sodium	129. Oxyquinoline
87. Merbromin	130. Padimate a
88. Mercufenol chloride	131. Pambron
89. Mercuric chloride	132. Pantothenic acid
90. Mercuric oxide	133. Papaya enzymes
91. Mercuric salicylate	134. Papaya, natural
92. Mercuric sulfide	135. Para-chloromercuriphenol
93. Mercury	136. Parethoxycaine
94. Mercury oleate	Hydrochloride
95. Mercury sulfide	137. Parsley
96. Methapyrilene fumarate	138. Passion flower extract
97. Methoxyphenamine	139. Pennyroyal Oil
98. Hydrochloride	140. Pentylenetetrazole
99. Methoxypolyoxyethyleneglycol	141. Peppermint Oil and Sage Oil
100. 350 laurate	142. Pepsin
101. Methyl nicotinate	143. Peruvian balsam (Myroxylon balsamum var. pereirae balsam)
102. Methypyrilene Hydrochloride	144. Phenacaine Hydrochloride
103. Milk and molasses	145. Phenindamine Tartrate
104. milk solids, dried	146. Phenolate sodium
105. Molasses	147. Phenolphthalein
106. Molybdenum Glycinate	148. Phenoxyacetic acid
107. Monosodium L-Aspartate	149. Phenyl salicylate (Salol)
108. Mullein	150. Phenyl salicylate
109. Mustard oil (alltlishthiocyanate)	151. Phenyltoloxamine dihydrogen citrate
110. Mycozyme	152. Phenyltoloxamine Hydrochloride
111. Myrrh gum tincture	153. Phosphate fluoride
112. Myrrh tincture	154. Phosphorated carbohydrate
113. Natural estrogenic hormone	155. Phosphorus
114. Nickel-pectin	156. Phytolacca
115. Non-Fat Dry Milk	157. Picrotoxin
116. Nonylphenoxypoly (ethyleneoxy)	158. Pimobendan
117. ethanol iodine	159. Pine tar
118. Nonylphenoxypoly nonoxynol 9	160. Piperocaine Hydrochloride
119. Noscapine Hydrochloride	161. Pipsissewa
120. Nutmeg oil	162. Piracetam dihydrogen citrate
121. Nux vomica extract	163. Piscidia erythrina
122. Obtundia	164. Plantago ovata husks
123. Octyl triazone	165. Poloxamer-iodine complex
124. Oil of erigeron	166. Polydimethylsiloxane and poloxamer
125. Organic vegetables	167. Polyols, liquid
126. Orthophosphoric acid	168. Polyoxeyethylene laurate
129. Potash Lye	171. Potassium ferrocyanide
130. Potassium chlorate	172. Potassium salicylate

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|---|--|
| 173. Povidone-vinylacetate copolymers       | 214. Sodium diacetate                        |
| 174. Prolase                                | 215. Sodium dichromate                       |
| 175. Prune concentrate dehydrate            | 216. Sodium dihydrogen phosphate monohydrate |
| 176. Prune powder                           | 217. Sodium nitrate                          |
| 177. Psyllium                               | 218. Sodium octanoate                        |
| 178. Psyllium hydrophillic mucilloid        | 219. Sodium oleate                           |
| 179. P-T-butyl-m-cresol                     | 220. Sodium para-amino benzoate              |
| 180. Pyruvic aldehyde                       | 221. Sodium perborate                        |
| 181. Pyruvic Aldehyde 40% Aqueous           | 222. Sodium perborate monohydrate            |
| 182. Solution                               | 223. Sodium phosphate                        |
| 183. Racephpedrine Hydrochloride            | 224. Sodium potassium tartrate               |
| 184. Red petrolatum                         | 225. Sols, secondary                         |
| 185. Reosote                                | 226. Soy meal                                |
| 186. Rhubarb fluid extract                  | 227. Soybean protein                         |
| 187. Rhubarb, Chinese                       | 228. Squill preparations                     |
| 188. Rice pollishings                       |  |
| 189. Romohydrate                            |  |
| 190. Sabadilla, alkaloids                   |  |
| 191. Sage oil                               |  |
| 192. Salicyl alcohol                        |  |
| 193. Sanguinaria extract                    |  |
| 194. Saw palmetto                           |  |
| 195. Scopolamine aminoxide                  |  |
| 196. Hydrobromide                           |  |
| 197. Sea mineral                            |  |
| 198. Senecio aureus                         |  |
| 199. Senna syrup                            |  |
| 200. Serotonin Hydrochloride                |  |
| 201. Sesame Seed                            |  |
| 202. Shark liver oil                        |  |
| 203. Short Chain Fatty Acid                 |  |
| 204. Silver (see also argentyn)             |  |
| 205. Silver, colloidal                      |  |
| 206. Sodium 3, 4-dimethylphenyl- glyoxylate |  |
| 207. Sodium acetylsalicylate                |  |
| 208. Sodium aluminum chlorohydroxy lactate  |  |
| 209. Sodium aspartate                       |  |
| 210. Sodium biphosphate                     |  |
| 211. Sodium bisulfate                       |  |
| 212. Sodium borate monohydrate              |  |
| 213. Sodium caseinate                       |  |

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- 229. Triple dye
- 230. Triticum
- 231. Turpentine Oil
- 232. Turpentine, Venice
- 233. Uinolinium bromide
- 234. Ulose
- 235. Uva ursi, extract of
- 236. Valic acid
- 237. Vitamin A acetate
- 238. Vitromersol
- 239. Wheat germ
- 240. Wheat germ (triticum aestivum/vulgare extract)
- 241. White ointment
- 242. Woodruff
- 243. Yeast
- 244. Yeast cell derivative
- 245. Yellow mercuric oxide
- 246. Zinc caprylate
- 247. Zinc citrate
- 248. Zinc phenol sulfonate
- 249. Zinc picolinate
- 250. Zinc propionate
- 251. Zinc sulfide
- 252. Zirconium oxide
- 253. Zyloxin**

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**FDA 503(A) Process update and questions:**

**Dr. Paul Anderson 09-15-2018**

**A few basics and Q&A are below:**

1. This process affects compounding – NOT supplement companies (who are in a different “food chain”).
2. “Nutritional Supplements” have been reclassified by FDA (per their update on 09-12-2018) as ORAL DELIVERY ROUTE ONLY so can no longer be labeled for topical, suppository or other administration route.
3. Compounding (which these lists affect) is the act of altering, mixing or in any way changing or combining substances under sections <785> (non-sterile i.e. Oral, Topical, Vaginal, Rectal etc.) products or <787> (sterile i.e. Ophthalmic, Nebulized / Respiratory, Parenteral (IV, IM, SQ...) products.
4. “Compounders” include any pharmacy AND any healthcare provider or healthcare facility (i.e. not just for pharmacists any more). \* See 5-B below.

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5. So you the physician in regard to performing any sterile or non-sterile procedure fall under the FDA and State Board of Pharmacy regulations for <797> and <795>. This is a different set of rules, but directly affect this 503(A) process (since it makes you a “compounder”). [“traditional compounder”, defined as a licensed pharmacist or licensed physician”]
  - a. I go into this in depth and provide a 23 page explanation with references and appendices on all this in either the CNDA or OANP webinars produced for this topic. <https://stores.modularmarket.com/cnda/pw32-fda-usp-updates-for-sterile-products-in-the-physician-office-how-do-i-comply-p210.php>
  - b. This is why the physician office has to have a cleanroom complying with Low-Risk or Medium-Risk compounding procedures, depending on the compounding you perform. (This is outlined in the webinars mentioned above as well). Ref: -- International Academy of Compounding Pharmacists. 2014. - IACP Comparison of 503A and 503B The Drug Quality and Security Act of 2013 downloaded from: <https://cdn.ymaws.com/www.iacprx.org/resource/resmgr/imported/IACP%20Comparison%20DQSA%20503A%20and%20503B%2001202014.pdf>
6. OF NOTE: The 503(B) process some believe will “save” all this (i.e. bulk compounding) is totally separate and at the moment has almost no regulation, so you ‘may’ obtain non patient specific drugs from them now – but- it (503(B)) is actually only intended for emergency manufacture of certified drugs in shortage – not simply making Glutathione or B12 for office use (which could disappear at any moment should they enforce the rules for 503(B) pharmacies.
7. AND: This process does NOT apply to any FDA APPROVED SUBSTANCE WITH A USP-NF MONOGRAPH. So you will not see some common drugs or nutrients on here as they are FDA approved already and have USP-NF monographs (such as Ascorbic Acid for Injection).
  - a. A USP-NF “dietary supplement” monograph specifically does NOT qualify for this process.
8. FINALLY: Category-2 is the only group illegal now. 1 & 3 are in a very tenuous “safe harbor” and so may be compounded (IF a pharmacy can locate raw material with a specific label “suitable for compounding” which many substances are \*mysteriously\* having removed which is why you cannot get some things anyway.)

**This question is an excellent one to make explanatory comment on:**

***“I have been following this but now I am confused. Is the below list regarding IV only? [COMMENT: No, see bullet #3 above] And I don’t see things we use, most of us on a daily basis including IM such as...”*** [See commentary below:]

- B12: Cyano and Hydroxo forms are FDA/USP approved drugs. They are exempt. Methyl B-12 is not approved, see awaiting hearings #14 below.
- Amino Acids: Mixed AA like FreeAmine, Aminosyn etc. are FDA-USP approved drugs. Some single amino acids are approved in one form and not another (i.e. L-cysteine is as is NAC)

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- Calcium: Calcium Gluconate and Chloride are FDA-USP approved drugs so exempt but #31&32 in Cat-3 below are unapproved and as they are on Cat-3 never will even have a hearing. So they are “automatically illegal”.
- Magnesium: Chloride and Sulfate forms are FDA-USP approved (so exempt) but # 74-77 on Cat-3 below Magnesium ascorbate, Magnesium bisglycinate, Magnesium bisglycinate dehydrate, Magnesium glycinate are not (so never a chance to be available).
- B5: Dexpanthenol injection is FDA-USP approved BUT Pantothenic acid #132 on Cat-3 below is not and will not have a hearing. So if your patient needs a plain B5 injection compounded without dexpanthenol preservative it would be illegal to possess or compound.
- B6: Pyridoxine is FDA-USP approved. P5P was approved for all routes of administration on 09-12-18 (#12, Cat-1 “yes” list).
- Selenium: Selenium injection is FDA-USP approved.
- NS: NS, D5, .45NS LR etc. are all FDA-USP approved
- MIC: Each ingredient would need to be approved. Methionine and Inositol have USP-NF monographs so are exempt. Choline only has a “dietary supplement” USP monograph (see bullet ‘7a’ above - so it is up for hearing (#8 on Cat-1 “Awaiting Hearings” below). If it is not approved it cannot be included.
- “WHEN WILL THIS BE ENACTED?” I have asked every insider and expert and nobody knows. Guesses include anywhere from January 2019 (unlikely) to three years. Nobody knows, and FDFA won’t tell.
- FINALLY: ANYTHING not on the “approved list” and not FDA-USP approved will be illegal to compound even if it isn’t on Cat 1, 2 or 3 as unapproved. So if your favorite bulk substance to compound isn’t on any list (and not already FDA-USP approved) it’s automatically illegal to compound as soon as this is enacted.