

Compound Name	Immunogenicity?	Specific Health Risks?	Health Risk Details	Impurities Likely?
CATEGORY 2 — Bulk Drug Substances Under 503A/503B Interim Policies				
BPC-157	Y	N	Insufficient human safety data	Y
Cathelicidin LL-37	Y	Y	Detrimental effects on male fertility; protumorigenic in some tissues	Y
Cesium chloride	N	Y	Heart toxicity; cardiac arrhythmias; potentially fatal; low potassium levels	N
Chloral hydrate	N	Y	Dosing errors; oversedation; mortality (especially in children)	N
Diethylstilbestrol	N	Y	Multiple cancers	N
Dihexa acetate	N	N	No human exposure data; unknown harm potential	N
Domperidone	N	Y	Life-threatening cardiac arrhythmias; sudden cardiac mortality; transfers to milk	N
Edetate disodium	N	Y	Fatal medication mix-ups with edetate calcium disodium; fatalities reported	N
Emideltide (DSIP)	Y	N	No safety data for proposed routes	Y
Epitalon	Y	N	Aggregation risk; no safety data for proposed routes	Y
Germanium sesquioxide	N	Y	Contaminated with toxic inorganic germanium salts; nephrotoxicity (kidney injury); mortality	Y
GHK-Cu (injectable)	Y	N	Limited human data; unknown harm potential	Y
GHRP-2 (injectable/nasal)	Y	Y	Increased insulin requirement; mortality in critically ill patients; infection; pancreatitis	Y
GHRP-6	Y	Y	Elevated cortisol; increased blood glucose; decreased insulin sensitivity	Y
Ibutamoren mesylate	N	Y	Congestive heart failure risk; clinical trial terminated early due to safety signal	N
Ipamorelin acetate	Y	Y	Mortality when administered IV; serious adverse events reported	Y
Kisspeptin-10	Y	N	No safety data for proposed routes; unknown harm potential	Y
KPV	N	N	No human exposure data; unknown harm potential	N
Melanotan II	Y	Y	Melanoma; posterior reversible encephalopathy syndrome; sympathomimetic toxidrome; priapism	Y
Mechano Growth Factor Pegylated (PEG-MGF)	Y	N	No human exposure data	Y
MOTs-C	Y	N	No human exposure data; unknown harm potential	Y
Neomycin sulfate (parenteral)	N	Y	Nephrotoxicity; irreversible ototoxicity (hearing/balance); neuromuscular blockade; respiratory failure	N
Quinacrine HCl (intrauterine)	N	Y	DNA mutation; aplastic anemia; hepatitis; severe dermatitis; psychosis; cancers	N
Semax (heptapeptide)	Y	N	Limited safety data; unknown harm potential	Y
Thymosin beta-4 fragment (LKKTETQ)	Y	N	No human exposure data	Y
Tranilast	N	Y	Liver injury; blood disorders (leukopenia, thrombocytopenia, anemia); renal failure	N
OTHER BULK DRUG SUBSTANCES THAT MAY PRESENT SIGNIFICANT SAFETY RISKS				
AOD-9604	Y	Y	Serious adverse events reported (causality unclear)	Y
CJC-1295	Y	Y	Increased heart rate; systemic vasodilatory reaction	Y
Selank acetate (TP-7)	Y	N	Insufficient safety data for human use	Y
Thymosin-alpha 1 (Ta1)	Y	N	Inadequate safety information; unknown harm extent	Y
Ibutamoren mesylate	N	Y	Congestive heart failure risk; clinical trial terminated early due to safety	N
Ipamorelin acetate	Y	Y	Mortality when administered IV; serious adverse events reported	Y
Kisspeptin-10	Y	N	No safety data for injection	Y
KPV	N	N	No human exposure data	N
Melanotan II	Y	Y	Melanoma; posterior reversible encephalopathy syndrome; sympathomimetic toxidrome; priapism	Y
Mechano Growth Factor Pegylated (PEG-MGF)	Y	N	No human exposure data	Y
MOTs-C	Y	N	No human exposure data	Y
Neomycin sulfate (parenteral)	N	Y	Nephrotoxicity; irreversible ototoxicity (hearing/balance); neuromuscular blockade; respiratory failure	N
Quinacrine HCl (intrauterine)	N	Y	DNA mutation; aplastic anemia; hepatitis; severe dermatitis; psychosis; cancers	N
Semax (heptapeptide)	Y	N	Limited safety data	Y
Thymosin beta-4 fragment (LKKTETQ)	Y	N	No human exposure data	Y
Tranilast	N	Y	Liver injury; blood disorders (leukopenia, thrombocytopenia, anemia); renal failure	N
AOD-9604	Y	Y	Serious adverse events reported (causality unclear)	Y
CJC-1295	Y	Y	Increased heart rate; systemic vasodilatory reaction	Y
Selank acetate (TP-7)	Y	N	Insufficient human safety data	Y
Thymosin-alpha 1 (Ta1)	Y	N	Insufficient safety data	Y