CLAIMS

1. Crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide or crystalline (S)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV characterized as having a powder x-ray diffraction pattern with peaks at 6.83, 10.31, 11.30, 12.18, 12.98, 13.69, 15.11, 16.23, 17.60, 17.99, 20.70, 21.15, 21.68, 22.71, 23.79, and 24.86 degrees 2Θ.

2. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV of claim 1 having an average particle size distribution of about 10 μm or less.

3. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV of claim 2 having an average particle size distribution of about 1 μm or less.

4. A composition comprising the (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV of claims 1 to 3 and one or more excipients.

5. A method of making a composition, the method comprising admixing the (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV of claims 1 to 3 and an excipient.

6. An *in vitro* method of regulating gene expression of a gene of interest in an isolated host cell, the method comprising contacting said host cell with the composition of claim 5, wherein the host cell comprises a polynucleotide encoding a gene switch that comprises a ligand binding domain that binds (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide and said gene switch comprises an ecdysone receptor ligand binding domain.

7. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV of claims 1 to 3or composition of claim 4 for use in treating a disease, disorder, injury, or condition in a subject, wherein a host cell within said subject comprises a polynucleotide encoding a gene switch that comprises a ligand binding domain that binds (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide and said gene switch comprises an ecdysone receptor ligand binding domain.

8. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV for use or composition for use as claimed in claim 7, wherein said disease, disorder, injury, or condition is selected from the group consisting of cancer, metabolic-related disorder, kidney disease, anemia, autoimmune disorder, ocular disorder, blood disorder, neurological disorder, lung disorder, rheumatologic disorder, and infectious disease.

9. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV for use or composition for use as claimed in claim 7, wherein said gene switch further comprises a ligand binding domain that dimerizes with said ligand binding domain that binds (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide.

10. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV for use or composition for use as clamed in claim 9 wherein said ligand binding domain that dimerizes with said ligand binding domain that binds (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide is a retinoic X receptor ligand binding domain.

11. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV for use or composition for use as clamed in claim 7, wherein said host cell further comprises a polynucleotide encoding a peptide, protein or polypeptide whose expression is regulated by said gene switch.

12. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV for use or composition for use as clamed in claim 11, wherein said polynucleotide encodes IL-12 or a subunit thereof.

13. A kit comprising the (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form IV of any one of claims 1 to 3.