What is Claimed Is:

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 comprising Form III, Form IV, Form V, Form VI, Form VII, Form VIII, or Form IX, or a mixture thereof, wherein:

Form III is characterized as having a powder x-ray diffraction pattern with peaks at 8.14, 8.52, 17.00, 18.56, and 22.19 degrees 2Θ;

Form IV is 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;

Form V is characterized as having a powder x-ray diffraction pattern with peaks at 9.38, 12.22, 13.18, 14.98, 17.32, 18.40, 22.41, 23.40, 23.55, 24.63, 24.79, 25.61, 28.02, and 31.77 degrees 2Θ;

Form VI is characterized as having a powder x-ray diffraction pattern with peaks at 9.38, 12.23, 13.25, 17.48, 18.41, and 22.41 degrees 2Θ;

Form VII is characterized as having a powder x-ray diffraction pattern with peaks at 8.18, 9.71, 13.30, 16.22, 17.73, 20.98, 21.20, 22.76, 24.68, 26.72, and 29.39 degrees 2Θ;

Form VIII is characterized as having a powder x-ray diffraction pattern with peaks at 10.05, 10.77, 14.06, 16.76, 18.11, 18.32, 18.43, 20.89, 21.71, 21.87, 24.07, 24.90, and 28.71 degrees 2Θ; and

Form IX is characterized as having a powder x-ray diffraction pattern with peaks at 7.06, 15.74, and 18.71 degrees 2Θ.

2. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide or (S)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 1, comprising Form III or Form IV, or a mixture thereof.

3. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 1, wherein said (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide is substantially pure Form III.

4. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 3, wherein said (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide is pure Form III.

5. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 4, wherein said pure Form III is characterized as having a powder x-ray diffraction pattern with peaks at 8.14, 8.52, 9.62, 11.02, 11.90, 12.16, 14.02, 14.62, 17.00, 17.88, 18.56, 19.02, 19.24, 20.51, 20.93, 22.19, 22.73, 23.22, 24.31, 24.53, 25.91, 26.22, 27.36, 27.73, 28.70, 30.84, 31.52, 32.30, 33.19, and 34.39 degrees 2Θ.

6. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 1, wherein said (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide is substantially pure Form IV.

7. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 6, wherein said (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide is pure Form IV.

8. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 7, wherein said pure Form IV is characterized as having a powder x-ray diffraction pattern with peaks at 6.83, 8.38, 8.91, 10.11, 10.31, 11.30, 11.89, 12.18, 12.98, 13.69, 14.14, 15.11, 15.81, 16.23, 17.60, 17.99, 18.60, 19.15, 19.66, 20.28, 20.70, 21.15, 21.68, 22.44, 22.71, 23.50, 23.79, 24.06, 24.86, 25.55, 26.53, 26.94, 27.21, 27.60, 28.67, 29.79, 30.50, 30.75, 31.55, 31.89, 32.78, 33.25, 33.48, 33.81, and 34.68 degrees 2Θ.

9. Amorphous (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide or (S)-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 of claim 9, wherein said (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide is substantially pure.

11. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 10, wherein said (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide form is pure.

12. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide form or forms of any one of claims 1-11 having an average particle size distribution of about 10 μm or less.

13. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide form or forms of claim 12 having an average particle size distribution of about 1 μm or less.

14. A composition comprising the (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide form or forms of any one of claims 1-13 and one or more excipients.

15. The composition of claim 14, wherein said one or more excipients comprise acetone or dimethyl sulfoxide.

16. The composition of claim 14, wherein said one or more excipients comprise one or more pharmaceutically acceptable excipients.

17. The composition of claim 16, wherein said one or more pharmaceutically acceptable excipients comprise Miglyol 812, phospholipon 90G, or tocopheryl polyethylene glycol 1000 succinate, or a mixture thereof.

18. The composition of claim 17, wherein said one or more pharmaceutically acceptable excipients consist essentially of Miglyol 812, phospholipon 90G, and tocopheryl polyethylene glycol 1000 succinate.

19. 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 or forms of any one of claims 1-13 and an excipient.

20. 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 14.

21. The method of claim 20, 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.

22. The method of claim 20, wherein the level of expression of said gene of interest is increased, relative to the level of expression of said gene of interest in the absence of said (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide.

23. The composition of claim 16 for treating a disease, disorder, injury, or condition in a subject.

24. The composition of claim 23, 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.

25. The composition of claim 24, 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.

26. The method of claim 21, wherein said gene switch comprises an ecdysone receptor ligand binding domain.

27. The composition of claim 24, wherein said gene switch comprises an ecdysone receptor ligand binding domain.

28. The composition of claim 27, 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.

29. The composition of claim 28, 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.

30. The composition of claim 29, wherein said retinoic X receptor ligand binding domain is a chimeric retinoic X receptor ligand binding domain.

31. The composition of claim 24, wherein said host cell further comprises a polynucleotide encoding a peptide, protein or polypeptide whose expression is regulated by said gene switch.

32. The composition of claim 31, wherein said polynucleotide encodes IL-12 or a subunit thereof.

33. A method of controlling insects, the method comprising contacting said insects or their habitat with an insecticidally effective amount of one or more crystalline polymorphic forms or amorphous forms of (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide or (S)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide, or a composition thereof.

34. A method of producing pure crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III, the method comprising: (a) equilibrating a suspension of crystalline or amorphous (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide for at least 0.5 hour in one or more non-solvate forming solvents at about 26°C or less; and (b) isolating said pure crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III.

35. The method of claim 34, wherein said solvents is a mixture consisting of heptane and toluene.

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

37. A kit comprising the composition of claim 14.

What is Claimed Is:

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 comprising Form III, Form IV, Form V, Form VI, Form VII, Form VIII, or Form IX, or a mixture thereof, wherein:

Form III is characterized as having a powder x-ray diffraction pattern with peaks at 8.14, 8.52, 9.62, 11.02, 11.90, 12.16, 14.02, 14.62, 17.00, 17.88, 18.56, 19.02, 19.24, 20.51, 20.93, 22.19, 22.73, 23.22, 24.31, 24.53, 25.91, 26.22, 27.36, 27.73, 28.70, 30.84, 31.52, 32.30, 33.19, and 34.39 degrees 2Θ;

Form IV is characterized as having a powder x-ray diffraction pattern with peaks at 6.83, 8.38, 8.91, 10.11, 10.31, 11.30, 11.89, 12.18, 12.98, 13.69, 14.14, 15.11, 15.81, 16.23, 17.60, 17.99, 18.60, 19.15, 19.66, 20.28, 20.70, 21.15, 21.68, 22.44, 22.71, 23.50, 23.79, 24.06, 24.86, 25.55, 26.53, 26.94, 27.21, 27.60, 28.67, 29.79, 30.50, 30.75, 31.55, 31.89, 32.78, 33.25, 33.48, 33.81, and 34.68 degrees 2Θ;

Form V is characterized as having a powder x-ray diffraction pattern with peaks at 9.38, 12.22, 13.18, 14.98, 17.32, 18.40, 22.41, 23.40, 23.55, 24.63, 24.79, 25.61, 28.02, and 31.77 degrees 2Θ;

Form VI is characterized as having a powder x-ray diffraction pattern with peaks at 9.38, 12.23, 13.25, 17.48, 18.41, and 22.41 degrees 2Θ;

Form VII is characterized as having a powder x-ray diffraction pattern with peaks at 8.18, 9.71, 13.30, 16.22, 17.73, 20.98, 21.20, 22.76, 24.68, 26.72, and 29.39 degrees 2Θ;

Form VIII is characterized as having a powder x-ray diffraction pattern with peaks at 10.05, 10.77, 14.06, 16.76, 18.11, 18.32, 18.43, 20.89, 21.71, 21.87, 24.07, 24.90, and 28.71 degrees 2Θ; and

Form IX is characterized as having a powder x-ray diffraction pattern with peaks at 7.06, 15.74, and 18.71 degrees 2Θ.

2. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 1, wherein said (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide is pure Form III.

3. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of claim 1, wherein said (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide is pure Form IV.

4. Amorphous (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide or (S)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide.

5. The (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide form or forms of any one of claims 1-4 having an average particle size distribution of about 10 μm or less.

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

7. A composition comprising the (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide form or forms of any one of claims 1-6 and one or more excipients.

8. The composition of claim 7, wherein said one or more excipients comprise one or more pharmaceutically acceptable excipients.

9. The composition of claim 8, wherein said one or more pharmaceutically acceptable excipients comprise Miglyol 812, phospholipon 90G, or tocopheryl polyethylene glycol 1000 succinate, or a mixture thereof.

10. 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 or forms of any one of claims 1-6 and an excipient.

11. A 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 7, 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.

12. Use of the crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide of any one of claims 1-6 for the manufacture of a medicament for treating a disease, disorder, injury, or condition in a subject, 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.

13. The use of claim 12, 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.

14. The use of claim 13, wherein said gene switch comprises an ecdysone receptor ligand binding domain.

15. The use of claim 14, wherein said host cell further comprises a polynucleotide encoding a peptide, protein or polypeptide whose expression is regulated by said gene switch.

16. The use of claim 15, wherein said polynucleotide encodes IL-12 or a subunit thereof.

17. A method of controlling insects, the method comprising contacting said insects or their habitat with an insecticidally effective amount of one or more crystalline polymorphic forms or amorphous forms of (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide or (S)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide, or a composition thereof.

18. A method of producing pure crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III, the method comprising: (a) equilibrating a suspension of crystalline or amorphous (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide for at least 0.5 hour in one or more non-solvate forming solvents at about 26°C or less; and (b) isolating said pure crystalline (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide Form III.

19. A kit comprising the (R)-3,5-dimethyl-benzoic acid N-(1-tert-butyl-butyl)-N'-(2-ethyl-3-methoxy-benzoyl)-hydrazide form or forms of any one of claims 1-6.