CLAIMS

What is claimed is:

1. A microprojection array suitable for transdermal drug delivery, wherein said microprojection array comprises a backing material with a plurality of attached microprojections wherein at least one of said microprojections comprises a coating of a formulation comprising [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

2. The microprojection array according to claim 1, wherein said microprojections comprise a polycarbonate polymer.

3. The microprojection array according to claim 1, wherein said microprojections comprise a liquid crystal polymer.

4. The microprojection array according to claim 1, wherein said microprojections comprise a base with a width greater than two times the width at the tip.

5. The microprojection array according to claim 1, wherein said microprojections comprise a base with a width greater than four times the width at the tip.

6. The microprojection array according to claim 1, wherein said microprojections comprise a base with a width greater than six times the width at the tip.

7. The microprojection array according to claim 1, wherein said microprojections are microneedles.

8. The microprojection array according to claim 1, wherein said microprojections are pyramidal in shape.

9. The microprojection array according to claim 1, wherein said microprojections have a rectangular base and rectangular tip.

10. The microprojection array according to claim 1, wherein said microprojections have a square base and square tip.

11. The microprojection array according to claim 1, wherein said microprojections have a flexural modulus of greater than 1,000 MPa (ISO 178).

12. The microprojection array according to claim 1, wherein said microprojections have a flexural modulus from 8,000 MPa to 12,000 MPa (ISO 178).

13. The microprojection array according to claim 1, wherein said microprojections have a flexural modulus from 9,000 MPa to 10,000 MPa (ISO 178).

14. The microprojection array according to claim 1, wherein said microprojections have a flexural modulus of between 9,000 MPa and 9,500 MPa (ISO 178).

15. The microprojection array according to claim 1, wherein said microprojections are more than 100 microns and less than 1,000 microns in length.

16. The microprojection array according to claim 1, wherein said microprojections are more than 400 microns and less than 600 microns in length.

17. The microprojection array according to claim 1, wherein said microprojections are 500 microns in length.

18. The microprojection array according to claim 1, wherein said array comprises between 100 and 500 microprojections.

19. The microprojection array according to claim 1, wherein said array comprises between 250 and 400 microprojections.

20. The microprojection array according to claim 1, wherein said array comprises between 300 and 375 microprojections.

21. The microprojection array according to claim 1, wherein said array comprises from 85 μg to 115 μg, 20 μg to 386 μg, or 85 μg to 230 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

22. The microprojection array according to claim 21, wherein said array comprises 100 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

23. The microprojection array according to claim 1, wherein said array comprises from 106.25 μg to 143.75 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

24. The microprojection array according to claim 1, wherein said array comprises from 127.5 μg to 172.5 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

25. The microprojection array according to claim 24, wherein said array comprises 150 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

26. Use of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2 for the manufacture of a medicament for use in administration to a mammal comprising contacting the skin of said mammal with a microprojection array according to claim 1, wherein said contacting occurs with sufficient force to cause penetration of one or more of said microprojections comprising a coating of said formulation into the skin of said mammal.

27. The use of claim 26, wherein said mammal is a human.

28. The use of claim 27, wherein said human has osteopenia or osteoporosis.

29. The use of claim 27, wherein said human is a post-menopausal woman.

30. The use of claim 27, wherein said human has glucocorticoid-induced osteopenia or osteoporosis.

31. The microprojection array according to claim 1, wherein said array comprises 366 microprojections, wherein said microprojections comprise a polycarbonate polymer, and wherein said coating comprises from 85 μg to 230 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

32. The microprojection array according to claim 1, wherein said array comprises 316 microprojections, wherein said microprojections comprise a liquid crystal polymer, and wherein said coating comprises from 85 μg to 230 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

33. The microprojection array according to claim 1, wherein said coating further comprises sucrose or hydroxyethyl cellulose.

34. The microprojection array according to claim 1, wherein said coating further comprises histidine or potassium chloride.

35. The microprojection array according to claim 1, wherein said array comprises at least 63.75 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

36. The microprojection array according to claim 1, wherein said microprojection array comprises from 80 μg to 450 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

37. The microprojection array according to claim 1, wherein said microprojection array comprises from 85 μg to 230 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

38. The microprojection array according to claim 1, wherein said microprojection array comprises from 20 μg to 386 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

39. The microprojection array according to Claim 1, wherein said formulation comprises 40 to 63 wt-% of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2 (SEQ ID NO.: 2).

40. The microprojection array according to Claim 1, wherein said formulation comprises 46 to 48 wt% or 50 to 62 wt-% of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2 (SEQ ID NO.: 2).

CLAIMS

What is claimed is:

1. A microprojection array suitable for transdermal drug delivery, wherein said microprojection array comprises a backing material with a plurality of attached microprojections wherein at least one of said microprojections comprises a coating of a formulation comprising [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

2. The microprojection array according to claim 1, wherein said microprojections comprise a polycarbonate polymer.

3. The microprojection array according to claim 1, wherein said microprojections comprise a liquid crystal polymer.

4. The microprojection array according to claim 1, wherein said microprojections comprise a base with a width greater than two times the width at the tip.

5. The microprojection array according to claim 1, wherein said microprojections comprise a base with a width greater than four times the width at the tip.

6. The microprojection array according to claim 1, wherein said microprojections comprise a base with a width greater than six times the width at the tip.

7. The microprojection array according to claim 1, wherein said microprojections are microneedles.

8. The microprojection array according to claim 1, wherein said microprojections are pyramidal in shape.

9. The microprojection array according to claim 1, wherein said microprojections have a rectangular base and rectangular tip.

10. The microprojection array according to claim 1, wherein said microprojections have a square base and square tip.

11. The microprojection array according to claim 1, wherein said microprojections have a flexural modulus of greater than 1,000 MPa (ISO 178).

12. The microprojection array according to claim 1, wherein said microprojections have a flexural modulus from 8,000 MPa to 12,000 MPa (ISO 178).

13. The microprojection array according to claim 1, wherein said microprojections have a flexural modulus from 9,000 MPa to 10,000 MPa (ISO 178).

14. The microprojection array according to claim 1, wherein said microprojections have a flexural modulus of between 9,000 MPa and 9,500 MPa (ISO 178).

15. The microprojection array according to claim 1, wherein said microprojections are more than 100 microns and less than 1,000 microns in length.

16. The microprojection array according to claim 1, wherein said microprojections are more than 400 microns and less than 600 microns in length.

17. The microprojection array according to claim 1, wherein said microprojections are 500 microns in length.

18. The microprojection array according to claim 1, wherein said array comprises between 100 and 500 microprojections.

19. The microprojection array according to claim 1, wherein said array comprises between 250 and 400 microprojections.

20. The microprojection array according to claim 1, wherein said array comprises between 300 and 375 microprojections.

21. The microprojection array according to claim 1, wherein said array comprises from 85 μg to 115 μg, 20 μg to 386 μg, or 85 μg to 230 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

22. The microprojection array according to claim 21, wherein said array comprises 100 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

23. The microprojection array according to claim 1, wherein said array comprises from 106.25 μg to 143.75 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

24. The microprojection array according to claim 1, wherein said array comprises from 127.5 μg to 172.5 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

25. The microprojection array according to claim 24, wherein said array comprises 150 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

26. Use of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2 for the manufacture of a medicament for the treatment of osteoporosis comprising contacting the skin of said mammal with a microprojection array of claim 1, wherein said contacting occurs with sufficient force to cause penetration of one or more of said microprojections comprising a coating of said formulation into the skin of said mammal.

27. The use of claim 26, wherein said mammal is a human.

28. The use of claim 27, wherein said human has osteopenia or osteoporosis.

29. The use of claim 27, wherein said human is a post-menopausal woman.

30. The use of claim 27, wherein said human has glucocorticoid-induced osteopenia or osteoporosis.

31. The microprojection array according to claim 1, wherein said array comprises 366 microprojections, wherein said microprojections comprise a polycarbonate polymer, and wherein said coating comprises from 85 μg to 230 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

32. The microprojection array according to claim 1, wherein said array comprises 316 microprojections, wherein said microprojections comprise a liquid crystal polymer, and wherein said coating comprises from 85 μg to 230 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

33. The microprojection array according to claim 1, wherein said coating further comprises sucrose or hydroxyethyl cellulose.

34. The microprojection array according to claim 1, wherein said coating further comprises histidine or potassium chloride.

35. The microprojection array according to claim 1, wherein said array comprises at least 63.75 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

36. The microprojection array according to claim 1, wherein said microprojection array comprises from 80 μg to 450 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

37. The microprojection array according to claim 1, wherein said microprojection array comprises from 85 μg to 230 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

38. The microprojection array according to claim 1, wherein said microprojection array comprises from 20 μg to 386 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2.

39. The microprojection array according to Claim 1, wherein said formulation comprises 40 to 63 wt-% of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2 (SEQ ID NO.: 2).

40. The microprojection array according to Claim 1, wherein said formulation comprises 46 to 48 wt% or 50 to 62 wt-% of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(1-34)NH_2 (SEQ ID NO.: 2).