the medical community to be critical in bodily functions, including, but not limited to, neuronal excitability, muscle contraction, membrane permeability, cell division, hormone secretion and bone mineralization. A disruption in calcium homeostasis, i.e., a calcium imbalance, is associated with many diseases, syndromes and conditions, including, but not limited to, cancer, heart disease and neurodegenerative disease.

[0006] In the past, calcium channel antagonists, which block the flow of calcium between cell interiors and interstitial fluid, have been widely-prescribed as pharmaceutical agents useful in the prevention of calcium-related disorders including hypertension, angina, asthma, migraines and neural deterioration. For example, nimidopine has been found to improve clinical symptomatology and cognitive functions in dementia by alleviating a calcium imbalance which causes neural deterioration. However, many of these calcium channel antagonists have unwanted side effects including, but not limited to, malaise, fluid retention, heartburn, erratic heart rate, dizziness, upset stomach and, in rare cases, fainting, fever and excessive bleeding.

[0007] Despite these advances, there is still a need for new and alternative therapeutics which alleviate or prevent calcium imbalance. In particular, pharmaceutical or nutraceutical compositions which have reduced side effects as compared to prior agents are desired and, if discovered, would meet a long felt need in the medical and nutritional health communities.

SUMMARY

[0008] The present disclosure provides compositions which are advantageous in the alleviation and/or prevention of symptoms or disorders associated with calcium imbalance and vitamin D deficiency. Such compositions include apoaequorin and vitamin D in combination with acceptable carriers for administration to a subject by a variety of routes.

[0009] Accordingly, the present disclosure is directed to compositions comprising effective amounts of apoaequorin and vitamin D in combination with an acceptable carrier. In certain embodiments, the present disclosure is directed to nutraceutical compositions including effective amounts of apoaequorin and vitamin D in combination with an acceptable carrier. In certain embodiments, nutraceutical compositions include, in addition to apoaequorin and vitamin D, at least one other component recognized as providing nutraceutical benefit such as, for example, an immune boosting agent, anti-inflammatory agent, anti-oxidant agent, anti-viral agent, or a mixture thereof. Apoaequorin and vitamin D compositions in certain embodiments are provided

in a unit dosage form selected from a tablet, a capsule, a solution, a suspension, a syrup, a beverage, an oral or ophthalmic formulation or an injection.

[0009a] In an aspect, there is provided a composition for treating a symptom or disorder associated with at least one of calcium imbalance and vitamin D deficiency, comprising: (a) an effective amount of apoaequorin; (b) an effective amount of vitamin D; and (c) an acceptable carrier.

[0010] In another embodiment, the disclosure is directed to a method for treating a symptom or disorder associated with calcium imbalance and vitamin D deficiency, comprising administering to a subject in need of such treatment an effective amount of apoaequorin and vitamin D.

[0010a] In a further aspect, there is provided use of a composition according to the present disclosure in the manufacture of a medicament for treating a symptom or disorder associated with at least one of calcium imbalance and vitamin D deficiency in a subject in need of such treatment.

[0011] Methods according to the disclosure are useful in treating a wide variety of symptoms or disorders associated with calcium imbalance and vitamin D deficiency, including but not limited to sleep quality, energy quality, mood quality, pain, memory quality. In certain embodiments, the calcium imbalance and vitamin D deficiency is physiologically-related to neuronal excitability, muscle contraction, membrane permeability, cell division, hormone secretion, bone mineralization, or cell death following ischemia. In such methods, apoaequorin and vitamin D are preferably administered to the subject in the form of a nutraceutical composition.

[0012] In yet another embodiment, the invention encompasses the use of apoaequorin and vitamin D for the manufacture of a nutraceutical composition for treating a symptom or disorder associated with calcium imbalance and vitamin D deficiency in a subject administered the nutraceutical composition. Exemplary symptoms or disorders treated by such compositions include those associated with sleep, energy, mood, pain, or memory.

[0012a] In another aspect, there is provided use of apoaequorin and vitamin D for the manufacture of a nutraceutical composition for treating a symptom or disorder associated with at least one of calcium imbalance and vitamin D deficiency in a subject administered said nutraceutical composition.

[0012b] In yet a further aspect, there is provided apoaequorin and vitamin D for use in the treatment of a symptom or disorder associated with at least one of calcium imbalance and vitamin D deficiency in a subject.

[0013] Accordingly, the present disclosure further contemplates apoaequorin and vitamin D for use in treating a symptom or disorder associated with calcium imbalance and vitamin D deficiency in a subject, including those symptoms or disorders associated with, e.g., sleep, energy, mood, pain, or memory in a subject.

[0013a] In another aspect, there is provided use of apoaequorin and vitamin D for the manufacture of a nutraceutical composition for treating a symptom or disorder associated with sleep, energy, mood, pain or memory in a subject administered said nutraceutical composition.

[0013b] In yet another aspect, there is provided apoaequorin and vitamin D for use in the treatment of a symptom or disorder associated with sleep, energy, mood, pain or memory in a subject administered said nutraceutical composition.

[0014] The present disclosure provides various advantages over prior compositions and methods in that it provides for the general improvement of a subject's mental and physical health.

[0015] Other objects, features and advantages of the present disclosure will become apparent after review of the specification and claims.

CLAIMS

What is claimed is:

1. A composition for treating a symptom or disorder associated with at least one of calcium imbalance and vitamin D deficiency, comprising: (a) an effective amount of apoaequorin; (b) an effective amount of vitamin D; and (c) an acceptable carrier.

2. The composition according to claim 1, wherein the composition is in the form of a unit dosage containing said effective amounts of the apoaequorin and vitamin D.

3. The composition according to claim 2, wherein: (a) the effective amount of apoaequorin in the unit dosage is about 10 mg to about 50 mg; and (b) the effective amount of vitamin D in the unit dosage is about 25 mcg to about 75 mcg.

4. The composition according to claim 3, wherein: (a) the effective amount of apoaequorin in the unit dosage is about 20 mg; and (b) the effective amount of vitamin D in the unit dosage is about 50 mcg.

5. The composition according to any one of claims 1-4, wherein the vitamin D is in the form of D3 cholecalciferol.

6. The composition according to any one of claims 1-5, wherein the unit dosage is a capsule.

7. The composition according to any one of claims 1-6, wherein the composition is a nutraceutical composition.

8. Use of a composition according to any one of claims 1-7 in the manufacture of a medicament for treating a symptom or disorder associated with at least one of calcium imbalance and vitamin D deficiency in a subject in need of such treatment.

9. The use according to claim 8, wherein the symptom or disorder is sleep-related and administration of the composition to said subject improves sleep quality in the subject.

10. The use according to claim 8, wherein the symptom or disorder is energy-related and administration of the composition to said subject improves energy quality in the subject.

11. The use according to claim 8, wherein the symptom or disorder is mood-related and administration of the composition to said subject improves mood quality in the subject.

12. The use according to claim 8, wherein the symptom or disorder is pain-related and administration of the composition to said subject alleviates pain in the subject.

13. The use according to claim 8, wherein the symptom or disorder is memory-related and administration of the composition to said subject improves memory quality in the subject.

14. The use according to claim 8, wherein the symptom or disorder is related to neuronal excitability, muscle contraction, membrane permeability, cell division, hormone secretion, bone mineralization, or cell death following ischemia.

15. Use of apoaequorin and vitamin D for the manufacture of a nutraceutical composition for treating a symptom or disorder associated with at least one of calcium imbalance and vitamin D deficiency in a subject administered said nutraceutical composition.

16. Use of apoaequorin and vitamin D for the manufacture of a nutraceutical composition for treating a symptom or disorder associated with sleep, energy, mood, pain or memory in a subject administered said nutraceutical composition.

17. Apoaequorin and vitamin D for use in the treatment of a symptom or disorder associated with at least one of calcium imbalance and vitamin D deficiency in a subject.

18. Apoaequorin and vitamin D for use in the treatment of a symptom or disorder associated with sleep, energy, mood, pain or memory in a subject administered said nutraceutical composition.