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FDA Approves First Dietary Supplement under New Drug Application with the Indication of Serious or Life-Threatening Illnesses

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Abstract

Background: Research began on botanical/herbal organisms to study plant cells. The idea behind this was that plant cells have basic similar actions as do animal cells (*i.e.*, both are Eukaryotic cells). These cells can show what activity is produced from the Technology/Innovation behind ImunStem, without risk to animals or humans, and still retrieve data to verify the theory. By using plants and studying plant cell activity, then later comparing plant cell, animal cells, and human cell responses, it thus shows activity for all cell structures. The activity was also studied from patients taking ImunStem for the indication of Serious or Life-threatening conditions or diseases. Patient medical report results showed an overall improvement in bodily function as blood report results were compared. Patients that were administered ImunStem showed improvement in their overall health and patients with chronic disease had reduced pain as ImunStem was administered over time. The pain was reduced because the body was in the healing process and a reduction in inflammation would occur during healing and the patient's health would improve. ImunStem was produced based on the theory that the product could rejuvenate the cell and bring the cell back to a homeostasis balance. This balance to the cell (through nutrition) can give the surrounding cells a homeostasis balance that may heal cells and tissues in the body. It is believed that the function of a Quantum Wave effect is explained through the discipline of Quantum Mechanics. The Quantum Wave may disrupt the subatomic particles that provide adhesion to allow the product through the cell wall and move to its target location. In Quantum Mechanics, particles have wavelike properties. The Schrödinger equation, for example, governs how these waves behave. **Methods:** Administration of ImunStem was given to patients in a life-threatening situation where no standard acceptable treatment was available and in which there was not sufficient time to obtain approval from the Institutional

Review Board. **Results:** ImunStem showed positive medical results for patients with Serious or Life-threatening conditions or diseases, which prompted the US Food and Drug Administration (FDA) to move forward so patients could be provided treatment that was not otherwise available to them from their physicians/doctors. ImunStem was applied for and received its New Drug Application (NDA) No.: 204701 with the indication of Serious or Life-threatening conditions or diseases and National Drug Code (NDC) No.: 70642-001-01 on July 02, 2018. Golden Sunrise submitted an NDA application on January 07, 2013, November 05, 2018, and April 03, 2020 with a request for FDA Fast Track designation, Breakthrough Therapy designation, Accelerated Approval designation, and Priority Review program process are the pathway allowing the ImunStem product to receive acceptance by the FDA.

Keywords

FDA, Serious or Life-Threatening Conditions or Diseases, Immunology, Dietary Supplements, Quantum Mechanics, Herbal/Botanical

1. Introduction

The novelty of ImunStem is that it is the first dietary supplement to be approved by the US Food and Drug Administration for Serious or Life-threatening conditions or diseases [1].

ImunStem stimulates the immune system throughout the body. ImunStem also helps blood flow through the system, especially in difficult regions such as body capillaries. ImunStem is a highly mobile compound that has been shown as a central nervous system and immune system stimulant. ImunStem can act alone safely or with other medical therapies to maximize efficacy and produce faster and lasting benefits to treat serious or life-threatening conditions or diseases by supporting immune system function. Physicians have observed that using ImunStem provokes a significant response, *i.e.*, a reduction in symptoms in patients with these diseases: autism, Alzheimer's, neuropathy, chronic lymphocytic leukemia, multiple sclerosis, Parkinson's, schizoaffective disorder, fragile-X syndrome, and a significant decrease of side-effects to chemotherapy for cancer. ImunStem has been shown to help reduce the loss of blood from surgical the wound and menstrual periods (shorter and lighter periods) [2] [3].

ImunStem indicate Serious or Life-threatening conditions or diseases [4]. Serious or Life-threatening conditions or diseases are defined as: a condition where the likelihood of death is high unless the course of the disease is interrupted and conditions or diseases with potentially fatal outcomes may occur, where the end point of clinical analysis is survival needs to be addressed. The criteria of life-threatening do not require the condition to be immediately life-threatening or to immediately result in death [5]. Rather, the patients must be in a life-threatening situation requiring intervention before review at a convened Instructional Re-

view Board meeting is feasible [6]. ImunStem has been given by licensed physicians/doctors to patients suffering from Serious or Life-threatening conditions or diseases [7]. ImunStem does not have harmful side effects and is very safe to use. It has shown efficacy and is admired by physicians/doctors who have administered ImunStem and have observed an improvement in patient outcomes, including improved quality of life [8].

The Quantum Wave effect is observed in nature. In the picture/photo below is a lake with winds distributed across the top of the water. This wind was in a relatively even distribution however there are distinctly two effects taking place. Notice the far end of the lake having what can be called a choppy water effect where the winds are pushing the water in an uneven pattern, however, the water close to the picture/photo being taken has a relatively calm pattern in which the wind is not catching or pushing the water but following over the water without disturbing the water. This wave effect can also be transferred to the quantum particle where a Quantum Wave is pushing or disrupting the particles to create a choppy wave effect [9]. After this occurs the wave effect is canceled and the body is noticed to have a calming effect [10]. This calming effect can heal damage or Deoxyribonucleic Acid/DNA repair in the human body (**Figure 1**). In the body, after calmness occurs, cells can have the ability to heal themselves. In a calm state, the body's cells can replace or heal those cells that are permanently damaged or destroyed [11].

2. ImunStem Clinical Pharmacology

2.1. Mechanism of Action

ImunStem is an herbal/botanical product, which has pathogenesis and homeostatic properties. ImunStem is taken in liquid oral doses for internal use. The

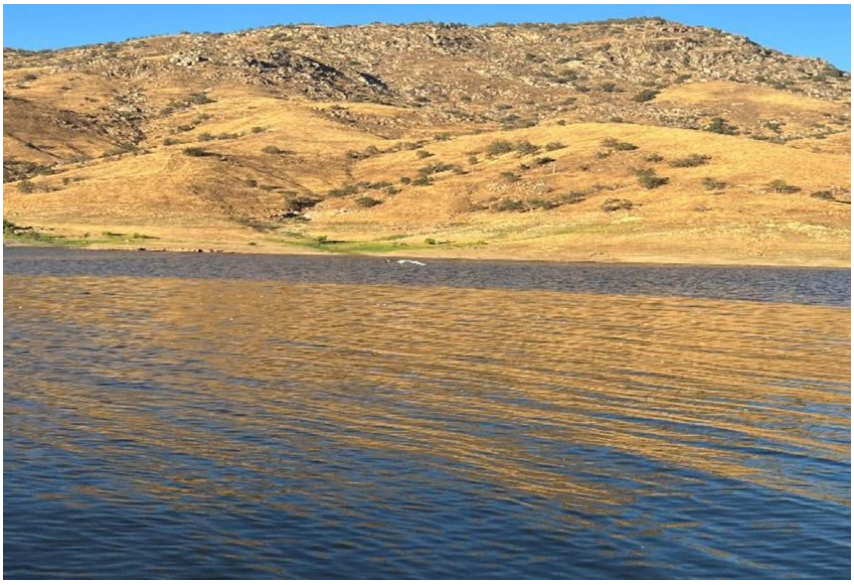


Figure 1. A picture of a lake showing choppy water as the wind blows yet in the foreground the water is only minimally affected and stays calm.

components of the drug substance that make the compound of ImunStem comprise the extraction of ingredients from Olive leaf (**Figure 2**), Yarrow flowers (**Figure 3**), Rosemary leaf (**Figure 4**), Yucca plant (**Figure 5**), and Cassia oil (**Figure 6**). The variety of components encompassing these botanicals has a wide use which provides antioxidant activity and a powerful positive effect on the immune system. ImunStem allows the active ingredients to disperse throughout the body and bloodstream; it also has a direct effect on immune cells and cellular functioning. ImunStem has immunostimulating properties *in-vivo* studies testing patients treated, increasing phagocytic activity and synthesis of helper cell function. ImunStem has been shown to enhance Deoxyribonucleic Acid/DNA repair before, during, and after chemotherapy drugs, toxic exposure, and chemical-induced damage. ImunStem modulates anxiety, initially including and then reversing these effects after long-term administration.

ImunStem has shown improvement in cellular Metabolism [12] and cellular-level Hypoxia [13]. ImunStem improves the uptake of nutrients in the cell which can improve the overall function of the body through oxygenation and nutrition. The effects of improved oxygenation of the cell and blood circulation may improve healing times for patients suffering from Serious or Life-threatening conditions or diseases. To reverse Hypoxia is to reduce or eliminate cellular dysfunction. An immune system that is overburdened results in body-wide 'inflammation', which describes decreased blood circulation, accumulation of metabolic waste such as radicals, aid-base imbalance, Localized Oxygen Deprivation [13], impaired energy production by the cells, etc. ImunStem can play an integral role in the hypothalamic activity, easing both parasympathetic and sympathetic nervous systems towards a state of homeostasis. Since blood pressure level is directly linked to the sympathetic nervous system, the lower blood pressure levels exhibited following the administration of ImunStem are compatible with the stabilization of sympathetic nervous system activity. The pulmonary benefits observed are likely due to the focus on deep breathing, which places less pressure on the lungs and increases lung capacity, as well as overall improvement seen in breathing efficiency. ImunStem reduces inflammation by affecting immune responsiveness through neuroendocrine factors. Its positive effect on balance is attributed to the improved use of vestibular input and wider stances.

2.2. Pharmacokinetics

ImunStem is readily absorbed into soft tissue matter when taken as an oral dose. ImunStem is a fast-acting product that is felt by the patient in just a matter of minutes. This is accomplished because ImunStem readily passes through membrane tissue by passive diffusion penetrating the circulatory system. ImunStem is a fast-acting substance. Once the onset of action takes place, patients can notice immediately calmness, improved breathing, mental clarity, and alertness (**Figure 1**). It is postulated that in arresting abnormal cellular mutation, the precursors for normal and enhanced cellular regeneration and cell division can be accele-

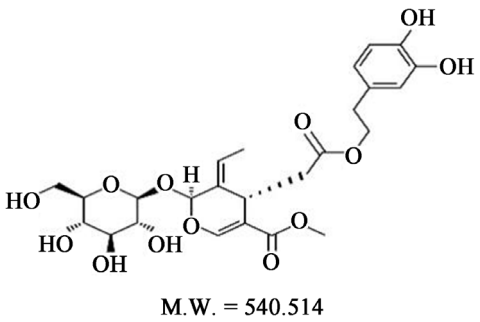
rated about the selective existing disease pathology. Observations of *in-vivo* testing that display the ability of ImunStem components to dissolve in hydrophilic substances propose that in the finished chemical form of the product and with its unique makeup, ImunStem produces a bipolarity that facilitates molecular diffusion through various permeable and selective membranes. It is therefore theorized that the combination of the bodies' thermal energy, particularly during variance mutation and inflammatory processes, potentiates the self-propelling of molecules by possible passive membrane transportation or passive diffusion of the ImunStem compound intact to cross the blood-brain barrier, also displaying lipophilicity (or lipophilic quality), to retain efficacy and activity for the central nervous system.

In-vivo studies involving treated test subjects have immune system activity in tests including blood tests and have provided the efficacious ability to improve immune system function while maintaining the cellular structure to tissue intact. These studies also reveal that ImunStem continues to provide improved immune system function with long-term use.

3. ImunStem [2]

Chemical Names and Chemical Structures

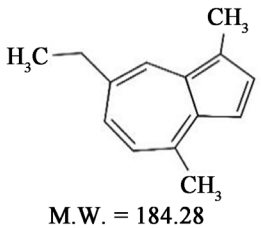
Oleuropein, a component of ImunStem is chemically described as 4S,5E,6S)-4-[2-[2-(3,4-dihydroxy phenyl) ethoxy]-2-oxoethyl]-5-ethylidene-6-[(2S,3R,4S,5S, 6R)-3,4,5-trihydroxy-6-(hydroxymethyl)-2-tetrahydropyranyl]oxy]-4H-pyran-3-carboxylic acid, methyl ester. Molecular formula $C_{25}H_{32}O_{13}$.



M.W. = 540.514

Figure 2. Chemical structure of Oleuropein.

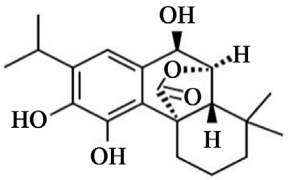
Achillea Millefolium, a component of ImunStem is chemically described as 7-Ethyl-1, 4-dimethyl azulene. Molecular formula $C_{14}H_{16}$.



M.W. = 184.28

Figure 3. Chemical structure of Yarrow flowers.

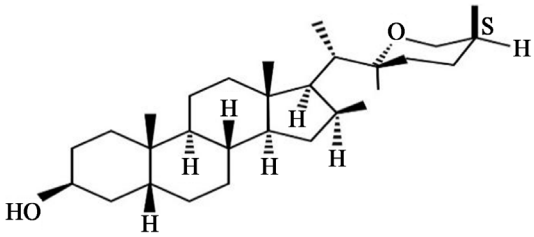
Rosmarinus Officinalis, a component of ImunStem is chemically described as [4aR-(4aa,9b,10a,10ab)]-1,3,4,9,10,10a-Hexahydro-5,6,9-trihydroxy-1,1-dimethyl-7-)1-methyl ethyl)-2H-10,4a-(epoxymethano)phenanthrene-12-one. Molecular formula $C_{20}H_{26}O_5$.



M.W. = 346.42

Figure 4. Chemical structure of Rosemary.

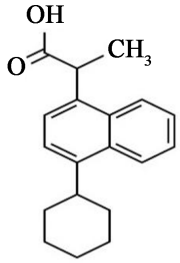
Sarsasapogenin Glycoside, a component of ImunStem is chemically described as 3-O-{[O-*α*-D-galactopyranosyl (1 → 2)]-[-O-*β*-D-galactopyranosyl(1 → 6)]-O-*β*-D-glucopyranosyl-(1 → 4)-*β*-D-glucopyranosyl}-(25S), 5*β*-spirostan-3*β*-ol. Molecular formula $C_{27}H_{44}O_3$.



M.W. = 416.64

Figure 5. Chemical structure of Yucca plant.

Cassia Oil, a component of ImunStem is chemically described as 2-methoxy-4-prop-2-enylphenol; [€-prop-1-enyl]benzene. Molecular formula $C_{19}H_{22}O_2$.



M.W. = 282.37678

Figure 6. Chemical structure of Cassia oil.

4. Methods Patient Background and Results

The observations compiled by licensed physicians/doctors and specialists in the medical field were entered and compared. It was observed that using ImunStem product provokes a significant response, *i.e.*, a reduction in symptoms for patients with Serious or Life-threatening conditions or diseases that required monitoring for doses and reactions by both the attending licensed physician/doctor,

registered nurse, or another specialist in the medical field [6] [7]. Evidence-Based Medicine is a set of principles and methods intended to ensure that to the greatest extent possible and clinical judgment or medical decision are made [14] [15].

4.1. Patient with Intermittent Explosive Disorder and Attention Deficit Hyperactivity Disorder

J.W. is a 10-year-old white male who began treatment with physician psychiatrist in Visalia California when he was 6 years old. He has been diagnosed the fragile-X syndrome. He was diagnosed with Attention Deficit Hyperactivity Disorder (ADHD) (F90.1), and Intermittent Explosive Disorder (IED) (F63.81). He has been treated over the years with Tegretol, Vyvanse, Zoloft, and Risperdal; he had a trial at another medical center of R Baclofen. Psychiatrists have also treated him with Gabitril, and Nudexta. He was taking Zoloft 150 mg in the morning, Risperdal 1 mg at bedtime, and Vyvanse 40mg in the morning. **Results:** On July 07, 2016 he started ImunStem twenty drops twice a day. On July 25, 2016, his mother reported as of this date that he was more focused and calmer. His level of perseveration has decreased dramatically. His mother stated that the other day he was organizing the DVD player in their home and "that's not like him."

4.2. Patient with Attention Deficit Hyperactivity Disorder

S.W. is a 64-year-old white male who began treatment with psychiatrist when he was 57 years old. He was initially diagnosed with anxiety disorder Not Otherwise Specified (F41.9) and ADHD without hyperactivity (F90.0). Stimulant medication was not effective in treating his focusing problems so Wellbutrin was used. Clorazepate was used to help with his anxiety. He did well with this combination of medicines until November 2014. He was diagnosed then as having diabetic neuropathy and was treated with Lyrica. He complained then that the medicine made him feel "fuzzy" and he could not be productive at work. In February 2015 he stopped the Clorazepate because he was afraid of having Alzheimer's disease and decreased the Wellbutrin on his own to decrease the fuzziness. He restarted the Clorazepate, eventually. In April 2016 he was taking Cymbalta 60 mg in the morning and Ambien 10 mg at bedtime. His family doctor had ceased the Wellbutrin and Chlorazepate. He was being treated at that point in time with methadone and Lyrica. He complained again of feeling fuzzy, tired, and unable to do his work. **Results**: In July 2016 he was started with ImunStem twenty drops twice a day. He reported two and a half weeks later that he had more energy and motivation. He was more productive and able to do his work and his pain had been reduced by thirty percent.

4.3. Patient with Schizoaffective Disorder and Polysubstance Abuse

S.R. is a 39-year-old white male who was first seen when he was 28 years old. He was transferred from another physician and was taking Wellbutrin-SR 100 mg

three times a day, Clozaril 600 mg at bedtime, Zoloft 200 mg in the morning, Topamax 100 mg at bedtime, and Aricept 20 mg at bedtime. He had a significant history of substance abuse, including marijuana, crack cocaine, mushrooms, and acid between the ages of 17 & 21 years old. He was diagnosed with schizoaffective disorder (F25.9) and Polysubstance abuse. He was treated with multiple medications over the years to try to help reduce his psychotic symptoms and increase his sociability. In June 2016 he was taking Vraylar 6mg in the morning, Fanapt 6 mg twice a day, Nudexta 20 - 10 twice a day, Chlorazepate 30 mg at bedtime, Prozac 40 mg in the morning, Clozaril 300mg at bedtime, Abilify 30 mg in the morning, and Gabitril 4 mg at bedtime. **Results:** On July 07, 2016, he was started with ImunStem twenty drops twice a day. He returned on July 21, 2016, reporting that he had decreased the Clorazepate to 15 mg at bedtime, his Prozac had been increased to 60 mg in the morning and he had been on ImunStem for two weeks as well as the other medications listed above. He reported, "My brain can keep up with my mind". He stated, "My brain is aware of my body". He reported increased energy, clearer thoughts, and non-racing thoughts. He also reported that he had a dry patch of skin on the back of his head that was now gone.

4.4. Patient with Alzheimer's Disease

L.H. is an 86-year-old white female who was diagnosed as having Alzheimer's disease and lives in a skilled nursing facility. She was on a liquid diet, sleeps most of the time, was confined to a wheelchair or a moving bed, and had intermittent episodes of agitation and flat facies. She has been treated with ImunStem ten drops twice a day for two and half weeks. Both staff and family report that she is less agitated, more alert, and smiling. **Results:** After thirty days on ImunStem the nurses report there are no longer any agitated episodes and she spends more time awake. On exam, the patient opened her eyes and focused on my face. There was no facial expression, but the patient appeared to try and move her lips as if she wanted to talk. (This was a new behavior). When I asked her to move her finger if she could understand me, she did.

4.5. Patient with Lymphocytic Leukemia

M.B. is a 69-year-old white male who has been treated for chronic Lymphocytic Leukemia for the last five years. He started taking ImunStem twenty drops twice a day in October of 2015. This was because of the concern about falling red blood cell counts and platelet counts. His white blood cell count, though elevated remained elevated, and fluctuant. **Results:** In October 2015, his red blood cell was four point zero five (4.05) and his platelet count was ninety (90). In April 2016 his red blood cell count was four point nineteen (4.19) and his platelet count was one hundred and five (105). It was felt that this was a significant increase in both his red blood cell count and platelet count. Please see Table 1 as follows:

Table 1. A chart ImunStem dated October 2015 and April, 2016.

	Date	Red Blood Count	Platelet Count
Before ImunStem:	October; 2015	4.05	90
After ImunStem:	April, 2016	4.19	105

Comparison of Red Blood Count and Platelet Count from October; 2015 through April; 2016.

4.6. Patient with Substance Abuse

R.B. is a 62-year-old white male who was first evaluated on August 19, 2016. He is taking Actos, Metformin, Lorstan, and Travastin for diabetes mellitus, high blood pressure, and glaucoma. There is no history of past substance abuse. He was interested in trying ImunStem to see if it would make any difference to his medical problems. He also complains of mild symptoms of depression including anergia, lack of motivation and feeling depressed about his physical problems. He was diagnosed with depressive disorder Not Otherwise Specified and started on ImunStem twenty drops twice a day. **Results:** The patient reported after eight weeks of ImunStem treatment that his energy and motivation have increased. He also reported that he was feeling less depressed. He reported that he was able to tolerate higher loads of carbohydrates without changing his diabetes medications, which also affect directly his energy and motivation.

4.7. Patient with Colon Cancer

J.O. is a 45-year-old white male diagnosed with advanced stage four colon cancer. He was diagnosed in January of 2016 and was not thought by the attending physician that he could have a positive outcome as the cancer was in mastitis and had spread throughout his body. His symptoms included a damaged liver, renal obstruction, lung polyps, anxiety, depression, and severe lack of energy. The patient received the first cycle of chemotherapy in March 2016. **Results:** In April 2016 the patient received his first dose of ImunStem administered orally at forty drops three times daily. At this time the patient showed noticeable improvement in overall health in minutes. The patient showed an improvement in energy levels as the next day he was playing basketball, mental focus, depression, and anxiety improved noticeably and his outlook on life was a positive hope. His tumors have shrunk and since the treatments of ImunStem and chemotherapy he has had no major side effects such as hair loss, debilitating constipation, depression, anxiety, weight loss, or nausea. He has not had to visit the emergency for complications except for a staph infection at his injection port. The patient is doing well and can function without interference with his normal lifestyle. The patient has been motivated to tell others of the benefits of taking ImunStem that it can help others with Serious or Life-threatening conditions or diseases (Table 2).

4.8. Patient with Autism/Seizure

J.A. is a 2.5-year-old male that was diagnosed with Autism/Seizure. His symptoms

Table 2. A chart ImunStem dated April 2017 and May thru November; 2017.

	Date	White Blood Count	Platelet Count
Before ImunStem:	April; 2017	5.7	70
After ImunStem:	May, 2017	6.7	78
	June; 2017	7.2	88
	July; 2017	7.5	111
	August; 2017	7.2	119
	September; 2017	10.9	157
	October; 2017	9.7	217
	November; 2017	7.7	187

Comparison of White Blood Count and Platelet Count from April; 2017 through November; 2017.

included: seizures, drooling, hyperactivity, disorientation, lack of pain stimuli, poor communication skills, and uncontrollable outbursts. He was diagnosed in October 2016 and was considered near the highest level of autism that provided government programs to assist with his mental state. He has an unknown regimen of prescription medications, and government assistance is provided for the re-education of motor skills. **Results:** In December 2016 he began oral administration of ImunStem at two drops per 12 fluid ounces of milk. In approximately four days his parents noticed he was aware of his surroundings and responded to the parents' directions. He was also noticed to cease drooling and felt pain in normal situations (such as falling while playing). He also had a reduction in seizures. He improved where no known seizures are being observed and he is more responsive to direction, his drooling has not returned and he is acting like a normal 2.5 years old.

4.9. Patient with Advanced-Stage Parkinson's Disease

S.R. is a 62-year-old black male that was diagnosed with advanced-stage Parkinson's disease. He was diagnosed 4 years ago and has had a steady progression of Parkinson's disease. The symptoms include, slurred speech, an unsteady (uneven) gait, memory loss, depression, tremors and occasional falling. He has taken the prescribed medication, which had only intermittent results. **Results:** In April of 2015 he began taking ImunStem oral administration at thirty drops twice a day. He states he feels more stable as he can walk on his own, has no more falling episodes, can focus better (clearer thought), has reduced tremors and has significantly reduced his depression. He has also returned to his previous employment.

4.10. Patient with Excessive Menstrual Bleeding and Painful Menstrual Periods

R.W. is a 16-year-old female that has had excessive menstrual bleeding and long

painful menstrual periods since Year-2013. She took Vicodin every month on the first day of her period. She had a debilitating pain that interfered with her lifestyle and activities and kept her confined to her home. **Results:** In October of 2016 she began taking ImunStem oral administration at thirty drops per day. After three weeks, her menstrual bleeding reduced and her pain had been alleviated. Her period duration had dropped by half and she could function in public as normal.

4.11. Patient with an Enlarged Prostate

R.G. is a 60-year-old male diagnosed with an enlarged prostate. He had been to multiple medical professionals that have treated him for everything from bleeding eyes to a heart attack. Physicians have recommended various surgeries for his prostate but the patient did not want to have these surgeries because of the possible adverse outcomes. **Results:** In October 2017 he was administered ImunStem while in the hospital being treated, within three minutes he felt an improved feeling in his prostate which felt like less pressure and less pain. He continued to improve over four months and no longer requires invasive procedures to alleviate prostate swelling. Please see the Table 3 as follows:

4.12. Patient with Multiple Sclerosis (MS)

E.B. is a 46-year-old white male diagnosed with Multiple Sclerosis (MS) in November 2016. He was the first suspect as having Lyme disease but upon further testing it was found to be MS. He experienced a continual degradation of motor function until he was bedridden, and he had almost total immobility of his legs and arms. The caregiver would assist the patient with all movement including bathroom activities. **Results:** The patient began taking ImunStem in October 2017 and showed a positive response for the first dose. Throughout treatments, the patient has experienced improved motor function to where he can sit in a wheelchair and move and can sit on the toilet without the aid of the caregiver. The patient continues to show marked improvement as the treatment progresses. The see Table 4 is as follows.

4.13. Patient with Esophageal Cancer

R.H. is a 54-year-old white male who was diagnosed on December 26, 2016, with esophageal cancer in stage two after the patient collapsed for no apparent reason

Table 3. A chart ImunStem dated October 2017 and December, 2017.

	Date	estimated Glomerular Filtration Rate	White Blood Count	Platelet Count
Before ImunStem:	October; 2017	15	6.36	136
After ImunStem:	December, 2017	40	8	332

Comparison of estimated Glomerular Filtration Rate, White Blood Count, and Platelet Count from October; 2017 through December; 2017.

Table 4. A chart ImunStem dated September 2017 and December, 2017.

	Date	White Blood Count	Platelet Count
Before ImunStem:	September; 2017	6.04	206
After ImunStem:	December, 2017	9.6	254

Comparison of White Blood Count and Platelet Count from September; 2017 through December; 2017.

Table 5. A chart ImunStem dated January 2017 and March, 2017.

	Date	White Blood Count	Mean Platelet Volume	Platelet Count
Before ImunStem:	January; 2017	6.4	6.9	375
After ImunStem:	March, 2017	9.4	8.4	332

Comparison of White Blood Count, Mean Platelet Volume and Platelet from January; 2017 through March; 2017.

and began spewing blood. The patient was rushed to the local emergency room where testing immediately began and the diagnosis was made. The patient refused standard medical cancer treatment (chemotherapies). **Results:** The patient began taking ImunStem on February 20, 2017, and showed improvements in both reports blood reports and medical scans. The physician at the hospital after reviewing the blood report and medical scans recommended: "resume regular diet" and receive another checkup in four weeks. Please see the Table 5 as follows:

NOTE: Administration of ImunStem products should always be under the supervision of a licensed medical practitioner, or a physician/doctor. Recommendations for ImunStem products are based on the following criteria: medical evaluation/assessment, diagnoses, monitoring, and medical report results of the patient, for treatment of Serious or Life-threatening conditions or diseases. Evidence-Based Medicine is a set of principles and methods intended to ensure that to the greatest extent possible and clinical judgment or medical decision are made.

5. Results and Discussion

To sell any new drug/medicine in the United State of America, Golden Sunrise Nutraceutical, Inc. (Golden Sunrise) must comply with the FDA under 21 *U.S.C.* §355(*a*) [16]. ImunStem product with an NDA No.: 204701 must contain complete medical report results and an Investigator's Brochure about the drug/medicine, including safety, effectiveness, the composition of the drug/medicine, description of how the drug is manufactured, and proposed labeling under 21 *U.S.C.* §355(*b*) [16]. The first time Golden Sunrise applied with FDA (form 356h) was on January 07, 2013 under 21 *U.S.C.* §355(*j*) [16], then it was filed with the Antiviral division; on November 05, 2018. The second application was submitted to FDA Regenerative Medicine Advanced Therapy (RMAT) division. The third applica-

tion was submitted to the Coronavirus Treatment Acceleration Program (CTAP) division on April 03, 2020, and on April 05, 2020, FDA CTAP assigned TRIAGED and Submission Tracking No.: 435. The FDA had approved ImunStem NDA No.: 204701 under the Accelerated Approval Program by regulations governing under 21 *C.F.R. FDA*-2013-*D*-0575 [17]. Traditional approval requires that clinical benefits be shown before approval can be granted. Accelerated approval is given to some new drugs for serious or life-threatening illnesses that lack satisfactory treatments. This allows an NDA to be approved before measures of effectiveness that would usually be required for approval are available [18]. On July 02, 2018, ImunStem received from FDA NDC Directory No.: 70642-001-01 Human Prescription Drug [19]. FDA agreed to Priority Review designation for ImunStem product with the notification of the New Drug Application on January 07, 2013 [20].

A small group of patients with serious or life-threatening conditions or diseases found that ImunStem dietary supplement improved the immune system and alertness immediately. Physicians/doctors have observed that using ImunStem provokes a significant response, *i.e.*, a reduction in symptoms in patients with these diseases; autism, Alzheimer's, neuropathy, chronic lymphocytic leukemia, multiple sclerosis, Parkinson's, schizoaffective disorder, fragile-X syndrome, and a significant decrease of side-effects to chemotherapy for cancer [2]. ImunStem has been shown to help reduce the loss of blood from the surgical wound and menstrual periods (shorter and lighter periods). Over hundreds of Serious or Life-threatening conditions or diseases, patients' test subjects administered ImunStem dietary supplement over time from a few weeks up to five years were made and included observations from attending physicians, nursing staff, caregivers, and Golden Sunrise medical personnel. Blood reports were also included and medications (if any) were documented. The observations compiled from family physicians/doctors and specialists were entered and compared with observations by Golden Sunrise medical staff. Safety was monitored and throughout these studies no adverse side effects were noticed. A representative number of test subjects were diagnosed with Serious or Life-threatening conditions

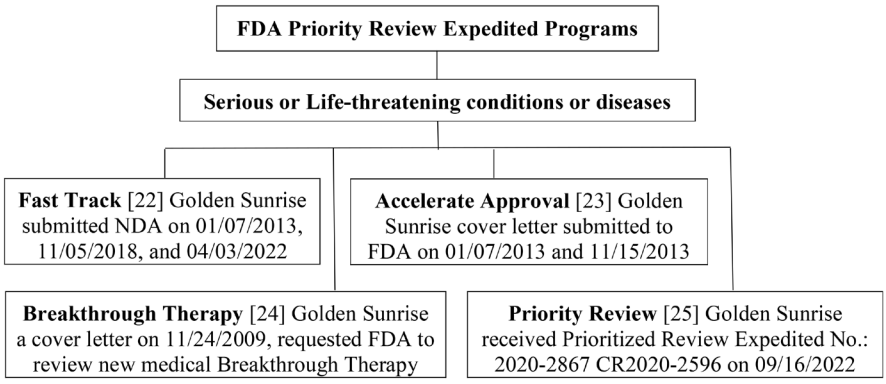


Figure 7. Expedited programs for regenerative medicine therapies for serious conditions [21].

or diseases. The FDA gave Golden Sunrise the FDA Expedited programs for regenerative medicine therapies for serious illnesses [21] (**Figure 7**). Fast track is a process designed to facilitate the development [22], in 1992 FDA instituted the Accelerated Approval regulations. These regulations allowed drugs for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint. Using a surrogate endpoint enabled the FDA to approve these drugs faster [23], Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s) [24], and A Priority Review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review) [25]. Under the 21st Century Cures Act patients suffering from Serious or Life-threatening conditions or diseases were treated and were required to have close monitoring by the attending doctor or medical professional of that field and by Golden Sunrise medical staff [26].

6. Nonclinical Genotoxicity

Purpose: The purpose of this study is to evaluate ImunStem for its ability to induce reverse mutation at the histidine locus in *Salmonella Typhimurium* tester strains both in the presence and absence of an exogenous mammalian metabolic system (S9) containing microsomal enzyme. **Conclusion:** Under the test conditions in this study, ImunStem was not mutagenic in the tested strains of the *Salmonella typhimurium*, histidine auxotrophs TA97, TA98, TA100, TA102 and TA1535 both in the presence and absence of metabolic activation system. The results indicated that, at the dose concentration of a 25-fold dilution to a 15,625-fold dilution of the original liquid, 100 µl/plate, ImunStem did not induce point mutations by base substitutions and/or frameshifts in the genome of these tested strains [2].

7. Conclusions

The administration of ImunStem to patients suffering from Serious or Life-threatening conditions or diseases has shown improved outcomes as observed by physicians/doctors. Patients have experienced a better quality of life and an extended timeframe to live an active lifestyle (for example, end-stage cancer patients being able to travel). ImunStem treatment to patients has generally shown a reduction or elimination of pain caused by an ongoing illness. This benefit has positive effects on the patient reducing stress and anxiety to help the healing process.

The paper "FDA Approves First Dietary Supplement under New Drug Application with the Indication of Serious or Life-threatening Illnesses" carries out nonclinical, clinical Pharmacology, chemical structures, clinical observation, and results of patients after treatment. The FDA has approved ImunStem NDA No.:

204701 under FDA Priority Review, Fast Track, Breakthrough Therapy, and Accelerated Approval program process and was the pathway including NDC No.: 70642-001-01.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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