October 4, 2005

Food and Drug Administration
Office of Orphan Products Development (HF-35)
5600 Fishers Lane
Rockville, MD 20857

Request for Humanitarian Use Device (HUD) designation

Dear OOPD Officer:

Indiana-based ABC Life Science, Inc. was formed in January 2005 to accelerate research and development and to commercialize a platform of promising therapeutic devices and drugs for the treatment of central nervous system (CNS) injury and disease.

ABC has designed the Extraspinal Oscillating Field Stimulator (OFS), a small electronic device, which could be the first effective treatment for acute (within 18 days of injury), complete spinal cord injuries. The device produces a weak electrical impulse across the injured area of spinal cord. It has shown significant promise in the stabilization, repair, regeneration, and re-construction of central nervous system tissue that can lead to an increase in neuron regrowth.

The OFS device is recommended only for patients with paraplegic and tetraplegic complete, acute spinal cord injuries (SCI) between Cervical Spine Level 5 (C5) and Thoracic Spine Level 10 (T10). Specific dangers and limitations in treatment of the other levels of SCIs are discussed in the Population Determination section of the attached HUD application. We have included historical and statistical data in this section to show that the number of affected patients each year is fewer than 4,000. We also detail other factors further reducing this number of injuries. This small target does not provide a large enough market and incentive for therapeutic development making it imperative to provide help or incentives for treatments that address the currently unmet medical needs of this patient population.

Therefore, we are requesting a HUD designation from your office. The enclosed documentation provides specific information regarding the indication and scientific rationale for use of the device, the explanation of the rare condition, and description of the specific patient population that will benefit from the use of the OFS device.

We look forward to working with you to bring this important breakthrough device to aid in the recovery of SCI patients.

Sincerely,

President and Chief Executive Officer
ABC Life Science, Inc.

123 Main Street, Suite 100 • Indianapolis, IN 46250 • 317.555.1234 • www.ABCinc.com • info@ABCinc.com

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1. Name and Address of Applicant

2. Contact Person

3. Indication for Use of the Device

The Extraspinal Oscillating Field Stimulator (OFS) is indicated for treating acute, complete spinal cord injuries.

4. Description of the Rare Disease or Condition

Despite aggressive research efforts, no treatment has been found to restore neurologic function for spinal cord injuries. The majority of spinal cord victims face years of lost independence and enormous medical costs.

The two major subdivisions of the spinal cord (shown in *Figure 1*) are centrally located gray matter containing nerve cell bodies, and the surrounding white matter, containing only the long processes of nerve cells – the axons. These are arranged in tracts that largely run parallel to each other and provide communication between the brain and the body. The figure to the right shows the spinal cord under compression. Because a cylinder of soft material experiences the most force at its center when squeezed from its sides - the most damage to the

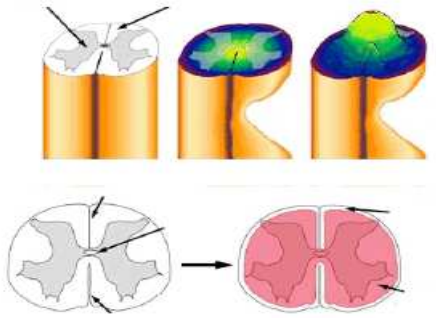

Figure 1

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cord is initially at its center. This damage then spreads out towards the edge by mechanisms called “secondary injury” and other processes such as bleeding, swelling, and inflammatory reactions – all hallmarks of soft tissue damage. This process, called central hemorrhagic necrosis, produces massive damage to the cord’s gray matter center, to much of the white matter, but spares a thin rind of white matter near the pial surface that is anatomically intact – but nonfunctional (often due to demyelization). The extent of a human spinal cord injury is usually less than 1 vertebral segment. The complete loss of nerve impulse “traffic” across this region produces the catastrophic loss in functions associated with the injury.

The American Spinal Injury Association (ASIA) defines standards to document the neurological extent of spinal cord injuries. The ASIA impairment scale scores patients on a scale of 1 to 5, with 1 being the score for complete injuries and 5 being the score for recovered injuries. A complete injury results in no sensory or motor function in the lowest sacral segments of the spinal cord. An incomplete injury results in partial preservation of sensory and/or motor function ($\geq$ 3 segments) below the level of injury and in the lowest sacral segments.

The OFS device is intended to treat only patients who have experienced acute and neurologically complete SCIs.

5. Description of the Device and the Scientific Rationale for its Use as Proposed

Conventional Therapy: Over the past 30 years, decompressive surgery and stabilization of the vertebral column, when required, have been the conventional means of therapy. High dose steroid therapy administered in acute injuries has the significant limitation of an 8-hour post-injury window to be effective. Neurologically complete patients are the most profoundly affected by SCI, and current therapeutic options such as physical therapy have had the least effect on these patients.

History: The use of an applied gradient of voltage to direct and control nerve fiber growth has a long and often conflicting history of reports prior to 1979. In 1979 and 1980, modern techniques in cell culture and biophysics proved even single nerve cells grown on a plastic substrate will produce new fibers towards the negative pole of a weak (microvolt to millivolts) electrical field imposed across them, and will redirect their fibers to grow in a new orientation when the axis of the voltage was shifted in mid-experiment. Importantly, a race of nerve support cells with long processes (called astrocytes) can also be directed to grow fibers in a specified direction by an imposed voltage gradient (a synonym for an electrical field). Formal scientific proof that a similar result could be achieved in the severed or crushed spinal cords of animals was published in the prestigious journal Science in 1980 using the simple nervous system of a primitive fish, followed by another article in Science in 1986 using adult guinea pigs. These data led to a clinical utility – the prototype of the first OFS device – tested in naturally produced paraplegia in dogs in blinded Veterinary clinical trials. The term “oscillating” refers to the fact that the polarity (i.e., negative / positive pole orientation) is reversed every 15 minutes to produce nerve growth in the spinal cord projecting towards the brain and in fibers projecting down the cord from the brain. Both of these oppositely directed “projections” of nerve fibers in the spinal cord are required for a beneficial clinical outcome. The responses of paraplegic dogs to OFS units were compared to the responses of dogs that were implanted with dummy units. A significant recovery

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of walking and stepping, pain perception, balance, and other clinical outcome measures was reported. Continuing development of the OFS device led to another similar Veterinary clinical trial in severe canine spinal injury – this time using a device destined for human use. The positive behavioral responses and safety of this trial (published in 1999) led to the first human trials of OFS which were begun in 2001 and published in January 2005 in the Journal of Neurosurgery.

OFS devices are undergoing a second round of implantation into 10 more "neurologically complete" patients. This second round of patients will establish the safety of the use of OFS in trauma patients. Based on prior animal studies, OFS implantation is indicated for use in the first 18 weeks following injury – but not long-term quadriplegia or paraplegia.

The OFS device: ABC Life Sciences, Inc. has designed the OFS, a small electronic device, which has demonstrated that a weak electrical impulse across the injured area of spinal cord can lead to an increase in the neuron regrowth. The OFS device is surgically implanted in the injured area of spinal cord within 18 days post injury and removed 15 weeks after the surgical implantation.

The OFS device is designed to use a weak electrical impulse across the injured area of spinal cord to reduce the formation of scar-forming cells at the injury site and to produce behavioral recovery from the spinal-cord injury through regeneration of spinal cord nerve processes.

The OFS unit (pictured in *Figure 2* on the top of the next page) consists of blocks of circuitry encased in a Teflon tube. Three pairs of 14cm long electrodes (Teflon insulated, tipped in medical grade platinum/iridium) extend out of the tube on one end. These possess expanded Silastic tabs for suturing to muscle.

A magnetic reed switch is utilized to "turn on or off" the device to enhance "shelf life." The unit is easily and safely sterilized by conventional techniques. The circuitry "blocks" within the Teflon "skin" control: The regulated output of steady DC current at each electrode pair (Reversal of the polarity of this current flow through the pair (Fail safe circuitry that shuts down the operation of the unit if it strays from nominal current output or oscillation (Telemetry in the form of an acoustic "beacon" that can be detected from outside the person (non-invasively) with a custom tunable amplifier to reveal the operation of the implanted unit.

Based on electrical measurements made in dogs, the total current output to achieve a beneficial electrical field was on the order of 600 µV. This is too much DC current to be delivered through a single pair of electrodes without the possibility of burning soft tissues. Thus three pairs of electrodes were utilized (200µV each pair) to achieve the proper magnitude of imposed Field. The operation of these three circuits is "timed" together, and the electrode pairs are color coded to insure that the surgeon implants them in an orientation such that all three pairs are additive (i.e. all current flow is simultaneously generated in the same direction).

The OFS device is surgically implanted in the musculature of the back, and the electrodes routed to the outside of the spine where each pair is fastened to vertebral facets two vertebral segments "above" and "below" the region of injury. The unit is implanted within the first 3 weeks of injury and removed approximately 14 weeks later.

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Specifically, the OFS device, when implanted within the musculature of the patient's back (external to the spinal cord), produces a weak electrical field (ca. 300-500 $\mu V/mm^2$) within the damaged region of the cord, whose polarity is reversed every 15 minutes. This therapy is known to produce nerve regeneration for limited distances across and through the spinal injury, to reduce the density of scar forming cells at the injury site, and to produce a behavioral recovery from both standardized transection injuries and compression injuries to the spinal cord.

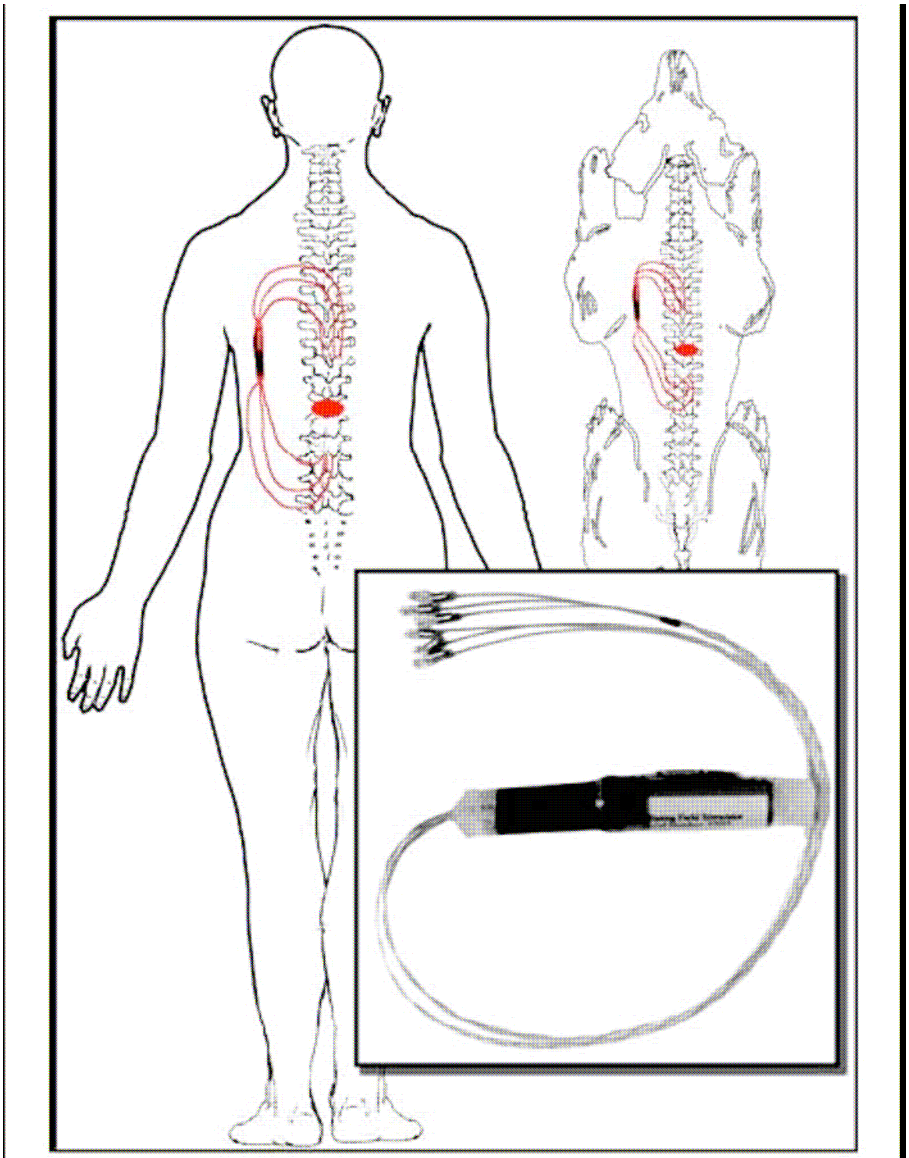

Figure 2

Four components of the OFS device come into contact with body tissues and blood during the 15 weeks of implantation:

1. The "jacket" or "casing" that encloses and seals the electronic components. This material is a 0.02 inch thick sheet of fluorinated ethylene propyene (FEP, otherwise known as Teflon®) extruded as a cylinder into which the electronics assembly is inserted.

2. The surface (insulation) of the insulated electrode leads. These lead wires or cables are commercially available pacemaker cable insulated with polytetrafluoethylene (PTFE, hereinafter, the insulated cables will be referred to as cables, "pacer cables or leads," whereas the uninsulated end that delivers current to tissues will be referred to as the "electrode").

3. The Nusil MED-1137 RTV silicone based medical grade elastomer, pressure injected into the ends of the FEP cylinder to seal it at its ends. This pressure injected silicone prevents moisture from penetrating into the OFS device's internal components.

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4. The uninsulated Platinum Iridium electrodes (medical grade 90% Pt, 10% Ir annealed alloy wire). This medical grade PtIr is free of mercury contaminants, with other trace metals in the alloy occurring in concentrations of less than 100 ppm.

6. Population Determination

Injury Level Determination: ABC recommends that the OFS device be used for patients with complete, acute spinal cord injuries (SCI) between Cervical Spine Level 5 (C5) and Thoracic Spine Level 10 (T10). Because of associated dangers treating injuries close to the tip of the spinal cord (below T10), the OFS device is simply not recommended. And, although the device is potentially effective for injury levels above C4, these patients typically are ventilator dependent requiring long-term care and significant financial and family commitment. We know that FDA is sensitive to these injury level cases and could allow for "compassionate exclusion" to include them at a later time, but for now, it is not recommended in this experimental phase.

In addition, OFS electrodes need to be placed on the two levels above and below the affected injury level. For example, for an injury on C8, treatment would include C6, C7, T1, and T2. For any injury above C4, electrodes would need to be placed on C1, which is the most devastating of all injury levels. The use of the OFS device would not be recommended in these dangerous situations.

Injury Population Determination: In *A Demographic Profile of New Traumatic Spinal Cord Injuries: Change and Stability over 30 Years*[1], Dr. Amie Jackson, et al., report that the global incidence rate of SCI has been estimated to be at most 40 cases per million population. Based on US population in 2004, this calculates to 11,000 SCI cases per year over the 30-year period from 1973 to 2003 as discussed in the article.

In *The 2004 Annual Statistical Report for the Model Spinal Cord Injury Care Systems*[2], numbers were gathered from the Collaborative SCI Survival Study database maintained at the National Spinal Cord Injury Statistical Center (NSCISC). Data used only included cases since 1973 and those treated within 1 year of injury (National, Page 33). According to the report, a total of 22,930 SCI cases were reflected in the database.

The American Spinal Injury Association's (ASIA) Impairment Scale was also used to quantify neurological function. The OFS device is intended to treat only patients who are given an ASIA impairment score of 1 for neurologically complete injuries.

Using the ASIA Impairment Scale by neurological level of lesion (National, Table 52 on Page 127), the following details were gathered:

Levels of Lesion	Tetraplegia		Paraplegia	
	Cervical (C1 to C8)		Thoracic (T1 to T12)	
	High (C1 to C4)	Low (C5 to C8)	High (T1 to T6)	Low (T7 to T12)
ASIA Score 1 Complete	1767	2946	2419	3106
ASIA All Scores Total Injuries	4129	7567	3181	4742

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Calculated Annual Score 1 Complete Cases	848	**1413**	**1160**	**1490**

Note: Annual Score 1 Complete Cases were calculated by dividing the number of complete (score 1) cases into the total 22,930 cases in the entire database: for example, 1767/22,930 = .077. This number multiplied by the estimated 11,000 SCI cases per year provides a more accurate number of cases each year: for example, .077*11,000=848.

According to these calculations, the annual patient population is approximately 4,063 (1,413+1,160+1,490). However, because the OFS device is intended to treat only a portion of the tetraplegic (C5 to C8) complete and a portion of the paraplegic (T1 to T10) complete, this further reduces the affected patient population.

Using the Neurological level of lesion at discharge – thoracic levels (National, Table 50 on Page 121), the following details were gathered:

Thoracic Level of Lesion OFS intended to treat											
	High						**Low (to T12)**				
Level	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**	**T7**	**T8**	**T9**	**T10**	**Total**
Scores 1-5 Cases in Database	355	263	405	882	597	679	465	636	412	896	7923
Calculated Score 1 Cases Only	270	200	308	670	454	516	305	417	270	587	5523
Calculated Annual # of Cases (T1-T6)	129	96	148	322	218	248					**1160**
Calculated Annual # of Cases (T7-T10)							146	200	129	282	**760**

Note: Calculated Score 1 Cases Only was calculated by multiplying Scores 1-5 Cases in Database by the percentage of total represented in Table 52: Thoracic High = 76%, Thoracic Low = 65.5%.
Note: Annual Cases were calculated by dividing the number of Score 1 ONLY cases into the total 22,930 cases in the entire database. For example, for T1 cases: 270/22,930 = .0117. This number multiplied by the estimated 11,000 SCI cases per year provides a more accurate number of T1 cases each year. For example, .0117*11,000=129.

From these calculations, the annual number of Thoracic High (T1 to T6) cases each year is approximately 1,160. The annual number of Thoracic Low (T7 to T10) cases each year is approximately 760. This further reduces the targeted patient population to 3,333 (C5 to C8 = 1,413, T1 to T6 = 1,160, T7 to T10 = 760).

Additional factors (Jackson, 1740-1748) that result in an even smaller intended patient population include the following:

1. The OFS device is not intended to treat complete injury due to gunshot wounds and other penetrating injuries because the injuries are too massive and beyond cure.
2. The OFS device is not intended to treat pregnant patients due to high risks involved.

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3. The OFS device is not intended to treat patients with multiple life threatening injuries.
4. The OFS device is not intended to treat medically unstable patients such as patients with AIDS, cancer, myocardial infection within three months, uncompensated congestive heart failure, or previous neurological injury.

Furthermore, since the estimated new annual SCI cases have been based over a 30-year period, significant changes have taken place affecting the population determination. There has been a dramatic decrease in the number of complete SCI patients. 60% of all complete cases have been results of violence, motor vehicle collisions (MVCs) or sports injuries (Jackson, 1740-1748). Acts of violence (the most common reason for paraplegia complete injuries) and the number of diving accidents (the highest reason for tetraplegia complete injuries) have steadily decreased since 1990 (Jackson, 1740-1748).

Within the category of sports injuries, most tetraplegia complete instances were due to diving accidents. Numerous primary prevention programs and newer and safer residential pool designs have contributed to a reduction in the number of diving-related complete injuries (Jackson, 1740-1748). The percentage of all injuries that resulted from diving has steadily deceased – 9.5% from 1973 to 1979, 8.2% from 1980 to 1989, 5.0% from 1990 to 1999, and 3.9% from 2000 to 2003 (Jackson, 1740-1748).

Dr. Amie Jackson, et al., pointed out that the most recent study of SCI prevalence is now almost 10 years old and that there have been no recent nationwide studies of SCI incidences in the United States (Jackson, 1740-1748). Dr. Jackson, et al., also explained that the various state registries, supported by the Centers for Disease Control and Prevention (CDC), have published limited information, but have made no attempt to generalize the data to the entire United States (Jackson, 1740-1748). Therefore, Dr. Jackson, et al., believe that the total number of estimated complete injuries must have been dramatically reduced due to general statistics on the decrease in violence and diving accidents within the past decade (Jackson, 1740-1748).

In conclusion, research, including the analysis of historical data from the NSCISC, as well as the downward trend in the number of complete SCI cases resulting from diving accidents and violence reported each year, indicates that the patient population potentially affected by ABC's OFS device will be less than 3,300. This should qualify it as a Humanitarian Use Device.

7. Terms and Acronyms

Term/Acronym	Definition
ASIA	American Spinal Injury Association
CDC	Centers for Disease Control and Prevention
CNS	Central Nervous System
MSCIS	Model Spinal Cord Injury Systems
MVC	Motor Vehicle Collision
NSCID	National Spinal Cord Injury Database
NSCISC	National Spinal Cord Injury Statistical Center

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Term/Acronym	Definition
OFS	Oscillating Field Stimulator
SCI	Spinal Cord Injury

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*Note: This article was derived from the following materials:

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This publication was used as an official reference for OFS patient population determination. This report is a publication of the National Spinal Cord Injury Statistical Center, Birmingham, Alabama and was funded by the National Institute on Disability and Rehabilitation Research, Office of Special Education and Rehabilitative Services, U.S. Department of Education. Statistics presented in this report cover a 30-year period from 1973 to 2003.

*Note: This article was derived from the following materials:

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10. Copies of all cited references

Attached.

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