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U.S. FOOD & DRUG ADMINISTRATION ESTABLISHMENT INSPECTION REPORT

Bio-Energy Services Inc.
18727 Ventura Blvd
Tarzana, CA 91356
818-609-0906

Page: 1 of 17
FEI: 3003668912
Date: 8/21, 22, 26 & 9/10/02
PID: JRF VRM

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SUMMARY:

This was a District initiated for cause inspection of a Sponsor-Investigator of an investigational medical device. The device is known as the PAP-IMI or Papimi. It is allegedly being studied for the reduction of pain caused by a myriad of conditions. The firm claims the device delivers electro-magnetic energy into the body, although the science behind the device is not clear. The study is being conducted under the non-significant risk regulations.

LOS and CDRH became aware of the situation through phone calls and letters from the original IRB who terminated the study and individuals who were associated with Bio-Energy Services.

The head of the sponsor, Bio-Energy Services, is Mr. Charles (Chuck) Wallach, CEO. He also claims to be the principal investigator of the study and the solely licensed distributor in the United States of the PAP-IMI. Mr. Wallach did not stop the study when ordered to do so by the IRB, Biomedical Research Institute of America, San Diego, CA, via a termination letter, dated 06/07/02. The termination reasons included unanticipated adverse events, commercialization, lack of informed consent, and mis-leading claims. There are approximately 41 devices currently used in the study at an estimated 37 study sites located in at least 12 states, mostly in California, Texas, and Florida. All of the sites are reported to be under the auspices of one IRB.

The PAP-IMI device is imported from Greece. The device is reportedly manufactured by [redacted] Athens, Greece. [redacted] reportedly headed by the owner, Dr. Panagiotis (Panos) T. Pappas, owner of the patent (U.S. # 5,556,418) for the device. The PAP-IMI is reported to also be under clinical study in Europe. The device is declared to U.S. Customs as a "plant and seed germinator" on the entry forms. The device is air shipped and the port of entry is Los Angeles (LAX). The current model number designation for PAP-IMIs is the 600P.

Mr. Wallach maintains a website at www.papimi.com. Dr. Pappas maintains a website at www.papimi.gr.

This was the initial inspection of Bio-Energy services. The inspection resulted in the issuance of a fourteen item list of objectionable conditions on the FDA-483. The objectionable conditions included failure to suspend the study when ordered to do so by the IRB, lack of informed consent, inadequate monitoring of other study sites, and unauthorized deviations from the investigational plan. Records were collected to be reviewed for commercialization and mis-leading claims. Mr. Wallach promised corrective action.

DOC Sample 194351 was collected for regulatory consideration.

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BUSINESS HISTORY:

Bio-Energy Services, Incorporated, reportedly is a California corporation based on a March 18, 2002 filing with the California Secretary of State of a statement by domestic stock corporation. See **exhibit 1**. Mr. Charles Edward Wallach is listed as the Chief Executive Officer. Mr. Gerald Anderson is listed as Secretary. Mr. John Heurung is listed as the Chief Financial Officer. Mr. Wallach is the only director listed. The Agent for Service of Process is Mr. William H. Dailey, 8749 Halloway Drive, West Hollywood, CA 90069.

The OSCAR database shows a 510(k) was submitted on November 6, 1995 for the "Pap Ion magnetic inductor" by [redacted]. The K[redacted] was not cleared because it required unavailable clinical data. Mr. Wallach was CEO of Pap Electrodynamics, according to his website.

Bio-Energy Services is reported to have received IRB approval to do its non-significant risk study on or about May 24, 2001. This IRB was Biomedical Research Institute of America, 3110 Camino del Rio South, suite A215, San Diego, CA 92108 (619-282-9997). The study reference number is BDS PAP 001. This IRB in a faxed letter, dated June 7, 2002 terminated the PAP-IMI study. See **exhibit 2** for a copy of the termination letter. The reasons for the termination included misuse, failure to report adverse events, lack of informed consent, commercialization, and mis-leading claims.

Bio-Energy Services did not stop their study. We observed subjects receiving treatment during the inspection. Mr. Wallach said the study termination by the San Diego IRB was without cause. He provided us with a copy letter, dated June 12, 2002 he sent to the San Diego IRB which rebuts their reasons for terminating the study. See **exhibit 3** for a copy of the rebuttal letter. The termination and rebuttal letter are posted on Bio-Energy's website along with testimonial letters from a PAP-IMI study investigator (Dr. Minkoff, Clearwater, Florida) in support of Mr. Wallach.

We cited Bio-Energy Services' failure to stop the investigation as observation 1 on the FDA-483.

Mr. Wallach said that he was in the process of gaining IRB approval from a different IRB. This new IRB is known as Texas Applied Biotechnology Research Review Committee, 8303 Southwest Freeway, Suite 835, Houston, Texas 77074 (713-777-5477). We spoke with the chairperson, Ms. Joyce Heinrich, of the Houston IRB over the telephone on August 22. Ms. Heinrich stated that her IRB was considering approving the Bio-Energy study as a non-significant study.

Biomedical Research Institute of America IRB notified the FDA of concerns with the PAP-IMI study verbally and in a fax letter, dated April 5, 2002. The concerns noted in the letter included misuse and commercialization. See **exhibit 4** for a copy of this fax letter.

Subsequently CDRH, Office of Compliance (HFZ-343), sent Bio-Energy Services a certified letter, dated May 7, 2002. The letter notified Bio-Energy Services that a marketing clearance was required based on their apparent commercialization of the PAP-IMI. A written response within thirty days was requested. See **exhibit 5** for a copy of the certified letter.

Mr. Wallach was aware of the FDA letter to him as the head of Bio-Energy Services. Mr. Wallach said he had obtained an attorney to get an extension of the 30-day time limit to reply to the letter. Mr. Wallach provided us a copy of his unsigned response letter to the FDA, dated June 12, 2002. Mr. Wallach said he had signed the letter and forwarded it to the attorney for delivery to the FDA. We called the attorney, Mr. Jim Turner, 1424 16th Street, N.W., suite 105, Washington DC, 20036 (202-462-8800) on August 22, 2002. We left a live message with his secretary for Mr. Turner to call us. Our call has not been returned to date. CDRH has no record of receiving the response letter. See **exhibit 6** for a copy of this alleged response letter.

A complaint letter was faxed to CDRH/OC on or about July 16, 2002 from a former associate of Mr. Wallach. This letter alleges many study violations and provides the names and phone numbers of several individuals to corroborate the accusations. See **exhibit 7** for a copy of the complaint letter.

Based on our conversations with Mr. Wallach's import broker, [redacted] (also known as [redacted]), he gave them power of attorney to broker the entry of the PAP-IMI into the U.S. on October 15, 1999. [redacted] is able to identify [redacted] entries of a "plant and seed germinator(s)" to date by Mr. Wallach. Mr. Wallach told us that he declared the PAP-IMI as a plant and seed germinator because that designation assured the device could get into the country without being scrutinized as a medical device and that it really could cause seed germination. Mr. Wallach said he only used [redacted] Services to broker the importation of the PAP-IMI.

The PAP-IMI is manufactured by [redacted] Athens, Greece, according to Mr. Wallach. [redacted] is reportedly headed by the owner, Dr. Panagiotis (Panos) T. Pappas, owner of the patent (U.S. # 5,556,418) for the device. See **exhibit 8** for a copy of this U.S. Patent, approved on September 17, 1996. The device is not refereed to as the PAP-IMI in the patent, instead as an "apparatus for pulsed magnetic induction". The science of the output of this device is not clear. The Bio-Energy website implies the output is the full range of the electromagnetic spectrum, including x-rays. The apparatus purports to induce electrical activity within cells of the human body. Mr. Wallach claims this electrical activity is simply energy that the cells need to restore any pre-existing pathology. Mr. Wallach states Dr. Pappas is the inventor of the PAP-IMI and that it is being studied in Europe for pain relief.

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PERSONS INTERVIEWED:

This was an unannounced inspection. Credentials were presented and the Notice of Inspection was issued to Mr. Charles E. Wallach, President of Bio-Energy Services. Mr. Wallach told us he was the founder of Bio-Energy Services and ran the business and the study from the inspected site in Tarzana, CA. Mr. Wallach said he was in charge of the Tarzana facility and we observed him during the inspection to issue orders that were promptly carried out. These orders included the delivery of records to us that we requested to review and collect. Mr. Wallach told us he was responsible for the investigational plans for the PAP-IMI study. Mr. Wallach told us he was the principal investigator for the PAP-IMI study. Mr. Wallach told us he was responsible for monitoring the co-investigators at the non-Tarzana sites for the PAP-IMI study. Mr. Wallach told us that he personally made the arrangements for the importation of the PAP-IMI device from Greece.

The FDA-483 was issued to Mr. Wallach.

Mr. Mazen Khalil, Medical Advisor for Bio-Energy Services, was interviewed. Mr. Khalil told us he graduated from the University of Damascus (Syria) in 1994 as a medical doctor. He is not licensed to practice medicine in California although he told us he was working towards that goal. Mr. Khalil said that he had been working for Bio-Energy Services for about ten days when we first interviewed him on 08/22/02. He told us that he was not authorized to operate the PAP-IMI until he took the required training from Mr. Wallach on or about 08/30/02. His present job at Bio-Energy Services was to help patients complete their Study Entrance Form. Mr. Khalil said he was careful to not practice medicine such as giving a diagnosis.

Ms. [redacted] was interviewed. Ms. [redacted] resides at [redacted] Ms. [redacted] is the mother of infant [redacted] who was born on [redacted] This infant was reportedly diagnosed shortly after birth with a rhabdomyosarcoma. The tumor manifests itself on the right side of the back of his neck. The tumor was surgically removed and the baby was started on chemotherapy. Ms. [redacted] said that while on the chemo the baby developed an infection, probably via an indwelling catheter and was listless. She decided to stop the chemotherapy. The baby is now treated twice a day at Bio-Energy Services and is fed "all natural food", including special teas. Ms. [redacted] can not afford the PAP-IMI treatments. The baby is noted to have received at least 29 treatments with the PAP-IMI. Mr. Wallach does not charge her and in return Ms. [redacted] works part time at the Tarzana study site. Ms. [redacted] heard about the PAP-IMI from friends and relatives. She believes it will help cure her son of the cancer. Ms. [redacted] said no one at Bio-Energy Services told her that the PAP-IMI would cure her son. The treating oncologist was Dr. [redacted]. Ms. [redacted] said the doctor was upset when she had the chemo stopped.

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FACILITY:

The facility at 18727 Ventura Blvd, Tarzana, CA 91356 is a storefront in a strip mall of various retail shops. The image seen on the home page of Mr. Wallach's website is that of the entire strip mall. The mall is shaped like a "V" with Bio-Energy Services at the center of the V. Other shops include restaurants and sporting goods. See **photo 1** for a picture of the exterior of the facility.

The approximate area of the Bio-Energy suite is 4,000 sq. ft. We took photographs of the Bio-Energy facility See **photos 2 - 4.** The front half of the suite is set up in an open style so that one can actually treatments being given to subjects. The facility seems to be staffed by attractive men and women. The décor is a natural style with many plush looking plants. There is a large picture of Dr. Pappas behind the receptionist desk, which is offset against a well so as to maintain the open style. The rear of the suite contains the final assembly room and some apparent business offices.

INVESTIGATIONAL PLAN:

Exhibit 9 is a copy of the investigational plan while the study was under the purview of the San Diego IRB.

Exhibit 10 is a copy of the investigational plan submitted for approval to the Houston IRB.

We did a brief review if the plans and noted the following. Both plans are similar. Both plans roughly follow the outline as required in Part 812.25 for an investigational plan. Both plans state "the study objective is to test the safety, tolerance, and efficacy of the PAP Ion Magnetic Inductor (PAP-IMI), a non heat producing pulsed diathermy device on pain intensity, pain relief, range of motion, and reduction in swelling (if applicable) in subjects with acute and chronic pain." Pain conditions include reflex sympathetic dystrophy, joint injuries, chronic sprains, bursitis, chronic nerve I injuries, neuralgia, arthritis, fibromyalgia, and "other painful conditions and diseases."

There is no limit to the number of subjects in either of the plans. The subjects had to be over 18 years of age to participate under the first plan. This age was raised to 21 years in the second plan. A general examination of the subject will be performed prior to entry.

The subject is to undergo a six week period of treatment with the number of treatments between three and twenty-four. Treatments are planned to be every other day for the first three treatments. The treatment interval may be up to once a week after the third treatment. The subject finishes the study after the 24th treatment or when they are free of pain for 72 hours or greater. Three follow-up surveys, after treatment completion, are to be done at 90, 180 and 360 days.

Relief of pain is measured by a scale from 0 (no relief) - 11 (complete relief) that is related by the patient and documented into the case history forms.

We cited eight observations on the FDA-483 for deficiencies in the investigational plan or for deviations from the plan. See the FDA-483 section, observations 3 - 10. We also cited observation 14 for selling water "energized" by the PAP-IMI and this use not being mentioned in the plan.

Not cited on the FDA-483 was an apparent problem with the pain measurement. The investigational plan (page16 under item K in the old plan and page 18 under item K in the new) says that the subject's use of analgesics is allowed upon permission of the investigator. However, there are no guidelines for investigator to consider when giving such permission. One would expect most subjects suffering from pain would routinely use analgesics. It is illogical to study subjects for pain relief using the PAP-IMI while the subjects are using pain killers (analgesics) at the same time. Subject [redacted] is using Percoset and Oxycontin according to the information they entered on their Study Entrance Form.

INFORMED CONSENT:

Our review of Bio-Energy's study subject's case files yielded a deficiency in Bio-Energy's collection of informed consent agreements with study subjects prior to receiving PAP-IMI treatment. During the inspection Mr. Wallach stated that approximately 80 to 160 individuals were enrolled in the investigational study at his facility at any given time. This is an average of 120 individuals. Thirteen subject's case report forms were selected at random for our review. Of the thirteen subject's records reviewed by us, eight lacked any signed informed consent documents. The initials of the subjects lacking any signed informed consent are as follows: [redacted] and [redacted] Three of the thirteen case report forms contained informed consent documents signed by subjects after beginning treatment. The informed consent documents signed after the subject had begun treatment included the following subjects: [redacted] who entered study on 1/30/02 and signed the informed consent agreement on 4/05/02, [redacted] who entered study on 4/25/02 and signed consent on 6/5/02, and [redacted] who entered the study on 4/03/02 and signed the informed consent agreement on 4/22/02.

All of the above mentioned individuals received multiple PAP-IMI treatments before signing an informed consent agreement or never signed at all.

The lack of signed informed consent by the subjects before entering the study was cited on the FDA-483 as observation 2.

INVESTIGATOR AGREEMENTS:

The investigational plan itself does not provide for the qualifications of the clinical investigators, nor did any other available document. Mr. Wallach makes the decision as to whether an individual is qualified to be a clinical investigator of the PAP-IMI.

We found no instance where Bio-Energy Services did not obtain a signed investigator agreement. **Exhibits 11 & 12** are examples of the signed investigator agreements for the Houston IRB. The agreements do not contain the required curriculum vitae and financial disclosures of the investigators.

We cited the failure to have the investigator's curriculum vitae and financial disclosure as observation 11 on the FDA-483.

CASE REPORT FORMS:

Generally, there was a case report form being completed each time a subject was treated at the Tarzana site.

We noted that each subject's file also contained a Study Entrance Form. Unlike the lack of signed informed consents from the subjects, these forms were signed by the subjects. The form requires the signature and date by the subjects immediately below the following statement: *I understand the above, that I am doing research on myself, and I accept the results.* **Exhibit 13** is a copy of a blank Study Entrance Form.

We cited the inappropriateness of the above statement as observation 12 on the FDA-483. Examples of actual signatures on this form are found under the discussion of this observation in the Objectionable Conditions section of this Establishment Inspection Report.

CLINICAL MONITORING:

The PAP-IMI study reportedly began on or about May 24, 2001 when IRB approval was obtained. There were no records of clinical monitoring for the Tarzana study site or any of the other study sites.

Mr. Wallach stated that he and Mr. Ari Klein, DC, Oakland, CA was going to be the study monitors.

We cited the failure of the investigational plan to have written procedures for monitoring the investigation as observation 10 on the FDA-483.

GOOD MANUFACTURING PRACTICES:

Design controls are not exempt for investigational devices. Mr. Wallach said the PAP-IMIs do not arrive at Bio-Energy Services as a finished device. Bio-Energy Services does the final assemblies of the transformers and rectifiers into each PAP-IMI. There were no finished device testing records to verify that each final build of a PAP-IMI meets its intended design. There were written procedures for the transformer and rectifier assemblies. See **exhibits 14 & 15** for copies of these procedures. See **photo 5** for a picture of the PAP-IMI.

We cited the failure to establish design controls as observation 13 on the FDA-483.

ENERGIZED WATER:

We noted that Bio-Energy Services was selling bottled water that reportedly had been "pulsed" by the PAP-IMI. See **photo 6**. Mr. Wallach referred to the water as being "energized' by the PAP-IMI.

We cited the failure of the investigational plan to cover the water as observation 14 on the FDA-483.

INVESTIGATIONAL DEVICE LABELING:

There were three PAP-IMIs in the storefront available for treating subjects and one older model that was reportedly only used when the other three were in use. We observed another PAP-IMI in the back room under repair. We noted that only two of those devices contained the statement: *CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use.*

We noted that the three PAP-IMIs without the investigational device labeling were identified in Bio-Energy Services treatment logs with the last two or three characters of their serial numbers. These identifications were [redacted] and [redacted] We recorded the complete serial number from F3 as follows: 1202740R3M3C3MT3PM3F3. See **photo 7** for a picture of the label.

DISTRIBUTION:

Mr. Wallach provided us a list of the study sites. See **exhibit 16** for this list. We noted that Bio-Energy's website also has a list of study sites. See **exhibit 17** for the web list we downloaded and formatted. We compared the lists and noted they did not match. We then prepared our own list that noted the discrepancies between the two lists. See **exhibit 18** for our list. Mr. Wallach said the list he provided us was current and that the website list was somewhat outdated. Mr. Wallach states there are thirty-five study sites in the U.S. and four in Canada.

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IMPORTATION:

The PAP-IMI is imported from Athens, Greece. The manufacturer as seen on the invoice #270, dated 6/21/01, for serial number 1202740R3M3C3MT3PM3F3 i[redacted] Athens, Greece 11744. We noted other units had the manufacturer as Z Electrodynamics. Mr. Wallach told us that both of these companies were owned by Dr. Pappas and were essentially the same business with Z being the production division and Bio being the research and development division. See **exhibit 19** for copies of records relating to the importation through the port of Los Angeles (LAX) that were provided to us by Mr. Wallach. The import broker was[redacted] The shipper was A[redacted] The merchandise was declared as a plant and seed germinator. The cost of this PAP-IMI was $[redacted] No duties were paid as this PAP-IMI is exempt as agriculture merchandise.

A visit to [redacted] Airways determined that Mr. Wallach obtained the services of [redacted] on October 15, 1999. The database showed [redacted] entries through Pacific ports from Athens, Greece to date. T[redacted] of these entries were through LAX and one each for Seattle and San Francisco. No entries have been made through Pacific ports to date in 2002. Only [redacted] of the [redacted] entry records for Los Angeles were available because five of them were not able to be located by [redacted]. The records showed that [redacted] PAP-IMIs had been brought into the U.S. by Mr. Wallach and all of them were declared as seed germinators. The other [redacted] entries were either transformers or rectifiers for the PAP-IMIs. The transformers and rectifiers prices varied but were $[redacted] or less for each.

COMMERCIALIZATION:

Mr. Wallach told us that he charged the clinical investigators approximately $[redacted] for a PAP-IMI. He provided us an invoice, #10048, dated 04/24/02, that shows Dr. David Minkoff, Clearwater, Florida payed $[redacted] for a PAP-IMI plus another $[redacted] for training and technical support. No sales tax was paid. Noteworthy is that invoice 10048 indicates this PAP-IMI was shipped complete, with transformer and rectifier, directly to Florida and did not come through a Pacific port. We determined the serial number of this PAP-IMI was 1202740R27M27C27MT27PM27F27. See **exhibit 19** for a copy of the invoice. We pointed out to Mr. Wallach that records showed he was procuring the PAP-IMIs from Greece for approximately $[redacted] and selling them for approximately $[redacted] which indicates a substantial profit. Mr. Wallach said he was paying a lot more for the transformers and rectifiers to finish the build of the PAP-IMIs. Mr. Wallach also claimed to have a lot of business overhead costs so that he was at best breaking even with the study. Mr. Wallach provided us with **Exhibit 20,** which is a financial statement of his business. Mr. Wallach said the statement shows he is not profiting from the PAP-IMI investigation. Mr. Wallach charges the subjects $60 for a half hour treatment with the PAP-IMI or $480 for ten treatments. See **photo 8.**

ADVERTISING:

We collected a total of six papers, brochures, and testimonial letters from the lobby at the Tarzana site. See **exhibits 21, 22, 23, 24, 25 & 26.** See **photo 9.**

Exhibit 21 notes that Mr. Wallach was in pain from two back surgeries and then after three treatments he became free from pain, "never to return."

Exhibit 22 is a testimonial letter from a PAP-IMI user and states in part, "my body was finally burning off the deep pathogens, viruses, and other organisms that literally crawl into the depth of your cells in immune deficiency illness..."

Exhibit 23 is a paper by Dr. Shri Kant Mishra, MD purported by Mr. Wallach to be one of the world's leading neurologists. The paper claims the PAP-IMI has been found to be effective for rheumatoid arthritis, systemic lupus, and aging related disorders.

Exhibit 24 is the July 2002 issue of Bio-Energy's *Papimi Times* newsletter. The newsletter states the PAP-IMI "is a recently developed technology that allows micro-pulsing at one-millionth of a second, empowering the cell and its potential to safely heal and rejuvenate itself." Noteworthy is that the letter states the study is going to continue under [redacted] We called this "IRB" and spoke to Mr. [redacted] the owner. [redacted] is not an IRB but a consulting company for sponsors. Mr. [redacted] told us that he had put Mr. Wallach in touch with TABS.

Exhibit 25 is an illustrated brochure that claims the PAP-IMI "can provide relief from pain." It also cites an "Approval" from Canada's Medical Device Bureau.

Exhibit 26 is a brochure claiming the PAP-IMI has been shown to relieve pain in animals.

The web site, www.papimi.com, discusses the safety and effectiveness of the PAP-IMI.

IRB:

We did not make contact with the San Diego IRB during the inspection. Mr. Wallach had copies of the annual reports of the investigators to the San Diego IRB. We collected three such reports. See **exhibits 27 - 29.** Exhibit 27 is from Dr. Minkoff and it has a very short discussion on two subject's deaths. They were not filed as adverse events at the time. The death dates are not given in the annual report. This is believed to be one of the reasons for the IRB terminating the study.

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COMMUNICATIONS TO INVESTIGATORS:

Mr. Wallach provided us with copies of e-mail correspondence to the clinical investigators. See **exhibits 30 & 31.**

Exhibit 30 is dated 07/10/02 and asks Investigators Ann and Gary Sconyers, Grapevine, Texas to complete new forms for the [redacted] IRB. (As explained earlier in this report, [redacted] is not an IRB).

Exhibit 31 is dated 07/22/02 and asks investigator Lawrence Dorman, Independence, Missouri to complete new IRB forms. This e-mail goes on to say that Dr. Pappas was saying that pre-surgery treatments was shortening the recovery time by one-third to one-halve.

CE MARK:

We noted that the PAP-IMIs were CE marked. The PAP-IMIs do not have UL or CSA safety certifications. Mr. Wallach provided us, via fax, a copy of Z Electrodynamics declaration of conformity for the CE. See **exhibit 32.**

OBJECTIONABLE CONDITIONS:

The FDA-483 was issued to Mr. Wallach on September 10, 2002.

Observation # 1 reads as follows: *Failure to suspend your study when it was terminated by your IRB on June 7, 2002.* This observation is discussed in the Business History section of this report.

Observation # 2 reads as follows: *Failure to obtain informed consent signatures from your subjects before they received their first treatment in eleven of thirteen subject cases studies that we reviewed.* See **exhibit 33** for a copy of a blank informed consent form. This observation is discussed in the Informed Consent section of this report.

Observation # 3 reads as follows: *Failure to follow the investigational plan by treating an infant with a birth date of [redacted] The current investigational plan states that the subjects must be at least 21 years of age or older with acute and chronic pain.* See **exhibit 34** for the complete file on infant [redacted]. We verified from the [redacted] case worker, Ms. [redacted] that the infant has a diagnosis of rhabdomyosarcoma, underwent surgery to remove the tumor, was started on chemotherapy, and the chemo was stopped on orders from the infant's mother. Ms. [redacted] said the prognosis was never good but without the chemo it is expected to be terminal.

Observation # 4 reads as follows: *Failure to follow the investigational plan by not obtaining a diagnosis from a health care professional prior to the subjects being entered into the study.* See **exhibit 35** for sections of the file for subject [redacted] Page 2 of the Study Entrance Form is blank, including the line as to who made the diagnosis. There is no diagnosis recorded. This subject presented with a complaint of back pain. This subject is documented to have undergone at least fourteen treatments. The case report form for a treatment on 04/10/02 did not record the blood pressure because the patient "did not want to." Recording blood pressure before and after each treatment is required by the investigational plan (page 13 on the old plan, page 15 on the new plan).

Observation # 5 reads as follows: *Failure to follow the investigational plan by not conducting a general examination of the subjects prior to entry in the study.* See **exhibit 36** for sections of the file for subject [redacted] There is provision in the Study Entrance Form or any other document to record the results of a general examination. This subject notes they have diagnosed themselves with lower back pain. This subject has had at least 18 treatments. The treatment on 05/09/02 does not record the blood pressure before or after the visit.

Observation # 6 reads as follows: *Failure to follow the investigational plan by enrolling at least two subjects with hemorrhagic tendencies. Hemorrhagic tendencies is listed in the investigational plan as an exclusion.* See **exhibits 37 & 38** for sections of the file for subject [redacted] and [redacted] notes a chief complaint of "excessive bleeding." [redacted] has had at least 13 treatments. [redacted] notes "abnormal bleeding." TW-N has had 3 treatments.

Observation # 7 reads as follows: *Failure to follow the investigational plan by enrolling a subject who has a peptic ulcer. Peptic ulcer is listed in the plan as an exclusion if the ulcer has bled recently. The case report forms for this subject make no statement as to the ulcer bleeding.* See **exhibit 39** for sections of the file for subject [redacted] This subject notes they have experienced a peptic ulcer. This subject has had four treatments.

Observation # 8 reads as follows: *Failure to follow the investigational plan by not documenting the three follow up surveys at 90, 180, and 360 day intervals after a subject completes the study.* Page 13 of the old plan and page 15 of the new plan calls for the three surveys to be done for each subject.

Observation # 9 reads as follows: *Failure to follow the investigational plan's safety precautions in that after starting the probe, operators are advised to stand at least one meter (or three feet) away from the probe to avoid continuous daily exposure. We observed the operators to routinely stand next to the probe during treatment of the subjects or to actually hold the probe to the desired site on the subject.* See the old plan, page 9, and the new plan, page 11, for said precaution. See **photos 4 & 10** for views of operators standing next to a PAP-IMI during treatments.

Observation # 10 reads as follows: *Failure to include or reference in the investigational plan the written procedures for monitoring the investigation.* Neither the old plan or the new plan contains or references any written monitoring procedures.

Observation # 11 reads as follows: *Failure to include in the signed investigator agreements their curriculum vitae or their financial disclosure information.* Although documents showed that the clinical investigators were signing agreements, they did not include or reference any curriculum vitae or financial disclosure.

Observation # 12 reads as follows: *The disclaimer statement on the Study Entrance Form requiring the subject's signature to enter the study is inappropriate. The disclaimer statement says the subjects are doing research on themselves and they will accept the results. The subjects are not doing research on themselves. You are doing the research on the subjects.* See the Case Report Forms section of this report for a discussion on the Study Entrance Form signature statement.

Observation # 13 reads as follows: *Design controls, in particular design verification, per 21 CFR Part 820.30 are not being followed. You assemble the transformers and rectifiers for each Papimi but there are no finished device testing documents to verify that each Papimi you finish building meets its intended design.* See the Good Manufacturing Practices section of this report for a discussion design controls.

Observation # 14 reads as follows: *The investigational plan is incomplete in that it does not address the subject's use of water energized by the Papimi. We observed bottles of water for sale that were advertised as having been energized by the Papimi.* See **exhibit 40** that shows subject [redacted] bought two bottles.

DOC SAMPLE:

A documentary sample, 194351, is being prepared for regulatory consideration.

DISCUSSION WITH MANAGEMENT:

We held discussions with Mr. Wallach throughout the inspection as he was the primary contact. We noted that the subject population ranged from [redacted] to [redacted] and this indicated people were withdrawing from the study. Mr. Wallach replied that people were withdrawing from the study because they were free from pain after a few treatments so why should they come back. Mr. Wallach acknowledged that many subjects were not completing the treatments but this was wonderful because it proved the PAP-IMI relieved pain.

Mr. Wallach told us that his employees were very healthful from being around the PAP-IMI. He pointed out how rich looking the plants in the facility were and he attributed this to the PAP-IMIs.

Mr. Wallach said the PAP-IMI had helped his vision problems and that he was considering a plan to study the PAP-IMI for use to correct vision problems. Mr. Wallach also said the PAP-IMI worked very well on horses.

Mr. Wallach said that he had placed the PAP-IMI on his wife's abdomen during her pregnancy. He said his four year old daughter from that pregnancy was as smart as an eight year old because of the PAP-IMI.

We issued the FDA-483 to Mr. Wallach. Mr. Wallach was responsive and polite during the closing discussion on the FDA-483. Mr. Wallach was well versed to each comment noted on the FDA-483. He took his own detailed notes while we discussed the observations. His responses to each of the 483 observations were as follows.

1. Mr. Wallach states that he will have a written copy of his new IRB approval from TABS by Friday 9/13/02. He considered his failure to stop the study as a technical violation and the reasons for the termination to be invalid.

2. Mr. Wallach was unaware that consent signatures had not been collected. He will speak to the employees about this immediately. He said this had been an issue before and he thought it had been addressed.

3. Mr. Wallach said he was currently rewriting a section of the investigational plan to allow for humanitarian exemptions such as the case with the [redacted] infant.

4. Mr. Wallach said he will have to look into this. He believed that a formal diagnosis was only needed for serious conditions and that if someone came in after a simple sprain, they did not need a formal diagnosis.

5. Mr. Wallach said he would speak with the chiropractor, Dr. Randy Kemberling, who he keeps on call two days a week and ask why more detailed patient records have not been kept. We asked how Dr. Kemberling could see all of the subjects when he was just coming in twice a week. Mr. Wallach replied that if there was a serious question, then the subject would just have to come back when the Doctor was in. Mr. Wallach acknowledges he has no licensed MD on his staff.

6. Mr. Wallach will change the investigational plan so that hemorrhagic tendencies are not listed as exclusions. He no longer believes that the PAP-IMI posses a potential risk to people with bleeding disorders.

7. Mr. Wallach will change the investigational plan so that ulcers are no longer listed as exclusions. Mr. Wallach states that it is now believed that the PAP-IMI does not cause or promote internal bleeding.

8. Mr. Wallach said "guilty as charged" because he knows that the study is deficient in its follow up of patients. He said as soon as a new computer program is installed in his office this problem will be taken care of.

9. Mr. Wallach will change the investigational study. He said it has now been proven safe for employees to be in close contact with the device all day long. The only potential problem is the issue known to Mr. Wallach as transference. Wallach describes this phenomena as a period of matching oscillating wave patterns between a patient and an operator who are both in contact with the PAP-IMI wand. When the wand causes the patient and operators' cells to oscillate at the same harmonic frequency, it then becomes possible for the patient's illness or symptoms to be transferred to the operator. When this phenomena occurs, the operator often fells a strong emotional connection with the patient. It is possible for the patient's symptoms to be felt by the provider long after treatment has ended.

10. Mr. Wallach said this observations "makes sense". He thanked us for a good observation and stated that he will write and implement monitoring procedures.

11. Mr. Wallach said he thought this had been done. He said he would speak with employee Jennifer.

12. Mr. Wallach said he would correct the statement to show that Bio-Energy Services was doing the research.

13. Mr. Wallach said he would establish a finished device test. He said they made sure the devices were working properly even if they currently lacked the documentation.

14. Mr. Wallach was not aware that this was a problem. Mr. Wallach stated that he was confused by this regulation. He said that the "energizing" effect off the PAP-IMI on the water only lasted three days. After that the user must smack their water bottle a total of 80 or so times "like a tuning fork" and the "pulsed/energized" effect will come back. Mr. Wallach will look into the food regulations, or consult his lawyer to find the best way to market his water.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19900 MacArthur Blvd. Suite 300 Irvine, CA 92612 949-798-7600	08/21, 22, 26/02 & 09/10/02
	FEI NUMBER 3003668912
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	
TO: Mr. Charles E. Wallach, Founder & Chief Executive Officer	
FIRM NAME Bio-Energy Services Inc.	STREET ADDRESS 18727 Ventura Blvd
CITY, STATE AND ZIP CODE Tarzana, CA 91356	TYPE OF ESTABLISHMENT INSPECTED Sponsor-Investigator of an Investigational Medical Device

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Concerning the investigational device study for pain relief using the device known as the Papimi;

1. Failure to suspend your study when it was terminated by your IRB on June 7, 2002.

2. Failure to obtain informed consent signatures from your subjects before they received their first treatment in eleven of thirteen subject cases studies that we reviewed.

3. Failure to follow the investigational plan by treating an infant with a birth date of [redacted]. The current investigational plan states that the subjects must be at least 21 years of age or older with acute and chronic pain.

4. Failure to follow the investigational plan by not obtaining a diagnosis from a health care professional prior to the subjects being entered into the study.

5. Failure to follow the investigational plan by not conducting a general examination of the subjects prior to entry in the study.

6. Failure to follow the investigational plan by enrolling at least two subjects with hemorrhagic tendencies. Hemorrhagic tendencies is listed in the investigational plan as an exclusion.

7. Failure to follow the investigational plan by enrolling a subject who has a peptic ulcer. Peptic ulcer is listed in the plan as an exclusion if the ulcer has bled recently. The case report forms for this subject make no statement as to the ulcer bleeding.

8. Failure to follow the investigational plan by not documenting the three follow up surveys at 90, 180, and 360 day intervals after a subject completes the study.

9. Failure to follow the investigational plan's safety precautions in that after starting the probe, operators are advised to stand at least one meter (or three feet) away from the probe to avoid continuous daily exposure. We observed the operators to routinely stand next to the probe during treatment of the subjects or to actually hold the probe to the desired site on the subject.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	James R. Fleckenstein Vanessa R. Muller	James R. Fleckenstein, Investigator Vanessa R. Muller, Investigator	09/10/02

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TO: Mr. Charles E. Wallach, Founder & Chief Executive Officer

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Bio-Energy Services Inc.	18727 Ventura Blvd
CITY, STATE AND ZIP CODE Tarzana, CA 91356	TYPE OF ESTABLISHMENT INSPECTED Sponsor-Investigator of an Investigational Medical Device

10. Failure to include or reference in the investigational plan the written procedures for monitoring the investigation.

11. Failure to include in the signed investigator agreements their curriculum vitae or their financial disclosure information.

12. The disclaimer statement on the Study Entrance Form requiring the subject's signature to enter the study is inappropriate. The disclaimer statement says the subjects are doing research on themselves and they will accept the results. The subjects are not doing research on themselves. You are doing the research on the subjects.

13. Design controls, in particular design verification, per 21 CFR Part 820.30 are not being followed. You assemble the transformers and rectifiers for each Papimi but there are no finished device testing documents to verify that each Papimi you finish building meets its intended design.

14. The investigational plan is incomplete in that it does not address the subject's use of water energized by the Papimi. We observed bottles of water for sale that were advertised as having been energized by the Papimi.

THE OBSERVATIONS ON THIS FORM ARE NOT AN EXHAUSTIVE LIST OF OBJECTIONABLE CONDITIONS.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	James R. Fleckenstein Vanessa R. Muller	James R. Fleckenstein, Investigator Vanessa R. Muller, Investigator	09/10/02