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 3003668912
 9/10/02 JRF VRM

Sent via fax: 301 594 4672

James W. Easley
 U.S. Food and Drug Administration
 CDRH, Office of compliance
 OPMADB, HFZ-343
 2098 Gaither Rd.
 Rockville, MD 20850

In re: Mr. Chuck Wallach, Founder
 Bio-Energy Services, Inc., the PAP-IMI device
 18727 Ventura Blvd.
 Tarzana, CA 91356

The following points describe a serious situation that your office has noted via letter of May 7, 2002. In addition to selling the device which is not FDA approved, many other conditions exist of which your office should be aware.

- Chuck Wallach and colleagues continued to sell the machine at a Doctor's Convention in late May in Orlando, Florida, despite notice of May 7, 2002, from the FDA advising that "it has come to our attention that you are marketing a device that does not have FDA approval." The leasing agent, Ken Goodman, accompanied the group to Orlando in order to quickly approve prospective buyers' credit applications and approximately [redacted] machines were sold at this convention. [redacted] was in attendance at this convention and can verify this activity which included the selling of the machine and training without advising the participants of the orders from the FDA. [redacted] has asked me to send this information to you. He would like to talk with you. He is presently in [redacted] and can be reached at [redacted].
- Chuck Wallach, Founder of Bio-Energy Services, Inc., brags about how he has skirted the customs problem for delivery to the United States of the PAP-IMI, classifying the device as a "seed germinator" instead of a "medical device".
- Jennifer Runyon, secretary to Chuck Wallach and the personal interface with the Bio-Med IRB, San Diego, revealed some 8 weeks ago and prior to the letter of May 7, 2002, that the conditions of the Bio-Med IRB study required that there be no profit made during the study and that the PAP-IMI machines were not to be sold during the study. The employees were not aware of these conditions, including Mr. Johnny Heurung, who was the General Manager. Heurung came to the company February 1, 2002, and was a minor stock holder along with Jerry Anderson, National Sales Manager, and Chuck Wallach, Founder.
- Chuck Wallach and colleagues continued to sell and "train" buyers in the use of the PAP-IMI following the termination June 7, 2002, of the Bio-Med IRB study. Mrs. [redacted] attended this training session the second week in June along with several friends from [redacted]. She was shocked at the claims being made by Wallach and the inconsistencies of

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the presentation. Mrs. [REDACTED] about the PAP-IMI. Only after several queries to Johnny Heurung, the General Manager, did she learn that the Bio-Med IRB study had been terminated in addition to the notice from the FDA regarding "sale without approval". Mrs.

[REDACTED] immediately sent these [REDACTED]. Moreover, she informed Chuck Wallach by phone and by letter that she and her colleagues were insulted by the presentation/sales training made by Jerry Anderson, National Sales Manager. One of Mrs. [REDACTED]'s friends had recently had [REDACTED] and was experiencing recurrence [REDACTED]. Wallach assured these women that a study had been done in Europe where some 63 women had experienced complete cure from the [REDACTED] but he did not produce the documents of the study.

- Chuck Wallach and Jerry Anderson when queried about the IRB status after the June 7th letter, replied to the trainees and buyers that the termination of the Bio-Med IRB was irrelevant. Wallach stated that Stoneybrook in New York would commence a new IRB study June 10, 2002, and would take the material gathered to date, review it and put its endorsement on the case studies, overriding the Bio-Med decision of June 7, 2002, with specific reference about cancer patients.
- Chuck Wallach placed two concurrent half-page ads in recent Alternative Medicine magazine soliciting doctors to purchase/lease a PAP-IMI with only \$199.00 down, two months of \$99.00, and then a five-year contract for the balance of approximately \$47,000+. [REDACTED] Leasing of [REDACTED] had allocated \$5,000,000 for this leasing program until one of the prospective buyers, Ms. Linda Nam, who manages a dental clinic in Koreatown/Los Angeles, made application in two names creating a question. [REDACTED] Leasing company found out the PAP-IMI had been turned down by the FDA in 1996, and they rescinded the availability of the funds.
- Wallach declares that there will be so much demand for the PAP-IMI by participants in the study that the FDA will be forced to give approval to the device.
- The PAP-IMI is manufactured in a small garage-type facility in Athens, Greece, and quality control is seriously lacking. When the device was examined by a reputable manufacturer in the U.S., it was obvious such workmanship would not get UL approval or FDA approval or 501k approval.
- Of the most recent [REDACTED] machines shipped through the middle of June to the U.S., [REDACTED] had voltage leaks and other problems and had to be returned to Tarzana, California, office for repair.
- The machine is of such poor assembly that the impression it gives when you open it up is that it has been glued together.
- The inventor, Dr. Panos Pappas, attributes universal health recoveries to utilization of the device.
- Earlier shipments to buyers in [REDACTED] and [REDACTED] had wires misconnected and could not operate until, in the case of the buyer in [REDACTED], the PAP-IMI was tracked down to [REDACTED] the cabinet opened up and wire connections changed. The buyer of the unit in [REDACTED] was able to make the wire changes himself. However, the machine stopped working

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properly after only 200 hours of operation. [REDACTED] phone in [REDACTED]

- The PAP-IMI is not UL approved.
- The PAP-IMI uses an old-style transformer filled with oil, which frequently overheats and discharges PCB's at breakdown.
- Management at Tarzana sends the PAP-IMI devices to treat racehorses and then returns them to work on people without any cleanup to probe. Chuck Wallach claims that no viruses or bacteria can live on the probe and thus this is not a problem.
- Operators are instructed to cool the over-heated probe by immersing it in a bucket of water. The instructions from the inventor say it should be cooled by electric fan. Eventually, the plastic hose gets small breaks through which water can migrate to the body of the machine. Operators and participants have received voltage shocks as well as heat burns from the overheated probe.
- Operators are instructed in the manual to stay 3 meters away from the machine while in operation. This warning is not part of the training given by Wallach. Operators use their hands to hold the probe in place on the participants' shoulders and back, and as a result are receiving an excessive amount of energy to themselves in the course of a day. Several of the operators have complained that they are not feeling well and have sought help from their own doctors for their complaints, which consist of dizziness, fatigue and vague feelings of discomfort. [REDACTED] is one of the operators with such complaints. Her phone number is [REDACTED]. She sought the advice of Dr. Randy Kemberling, the chiropractor in attendance on Tuesday and Thursday at the PAP-IMI pain clinic, Tarzana. Dr. Kemberling has decided not to buy or even use the PAP-IMI in his practice. Dr. Kemberling's office number in Burbank is 818-563-6179.
- The device is supposed to be vented to the outside. This is not done at the Tarzana location. Sometimes there are as many as four devices in operation at one time.
- Promoter Chuck Wallach teaches new owners positions he recommends for placement of the PAP-IMI for treating cancer and other diseases. Wallach does not limit his presentation to pain relief.
- Chuck Wallach responds to almost every health problem described to him with the statement that the PAP-IMI delivers enough energy to cause the cell to have what it needs to repair any problem.
- Many participants quit the study because of the failure to get any results as well as cost. Following the first free session, the charges were \$60.00 per half hour. For participants over 65 years of age, \$48.00; over 80, \$38.00; over 90, no charge. Discounts were available at 10 sessions for \$480.00.
- Chuck Wallach traded treatments with a [REDACTED] in exchange for his services [REDACTED] the PAP-IMI training. This [REDACTED] had a [REDACTED] following several PAP-IMI treatments and underwent surgery to [REDACTED]. Wallach claims the PAP-IMI treatments saved his life.
- Salesman and now General Manager [REDACTED] sustained a severe shock from the PAP-IMI that nearly knocked him unconscious when he was administering to race horses at the race track in Los Angeles.

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- [REDACTED] of [REDACTED] received four PAP-IMI machines before finally receiving one that worked.
- Wallach justifies the high cost of the PAP-IMI explaining that the device uses two components that are triggers for the atomic bomb.
- Attorney William Dailey worked with Gen. Mgr. Johnny Heuring detailing the statements that should not be made during presentation/training. Jerry Anderson, in front of the trainees, removed all these notes with the remarks that they were unwarranted, incorrect, not appropriate and misleading. Johnny Heuring confronted Wallach with this information of Anderson's behaviour stating it was a cause for dismissal, and Wallach refused to take action.
- Several of the female employees endured sexual harassment from a male employee for many weeks without redress. [REDACTED] regularly gave participants additional advice including sexual advice which was of such a nature that several participants told him to get lost.
- Participants who presented themselves for the study with conditions such as cancer and AIDS were "treated". It mattered not what condition was presented. Chuck Wallach would declare, "We can take care of that!" or "My father had that 6 years ago and got rid of it." The elderly and people with conditions such as multiple sclerosis were given false hopes by Wallach.

With all this evidence over and above what you have seen from Chuck Wallach/Bio-Energy Services, Inc., with their ads and other activity, I only hope you intend to quickly stop them as they flaunt and ignore the law, continuing business as usual after the letters of May 7, 2002, and June 7, 2002, taking serious money from people unable to afford the \$60.00 for the half-hour treatments or the \$47,000+ for the PAP-IMI device.

Until the first of this year, I was interested in the PAP-IMI device, but as this evidence accumulated of lies and misrepresentation, I was no longer interested.

Each of the individuals cited with phone numbers has talked with me specifically about the concerns detailed in this letter.

This information is being provided in hopes that your bureau will quickly bring some justice and fairness to the situation on behalf of all those people whose hopes for relief or cures were raised by the claims of Wallach and Anderson.

Sincerely yours,

[REDACTED]

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