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Bio-Energy Services
3003668912
9/10/02 JRF VRM

FILE

biomed

Biomedical Research Institute of America
a non-profit corporation

IRB

June 7, 2002

Mr. Charles Wallach
Bio-Energy Services
18727 Ventura Boulevard
Tarzana, CA 91356

Re: **Termination of Study**
Bio-Energy Services, Inc.
Protocol No.: BDS PAP001

Dear Mr. Wallach:

The IRB committee has reviewed additional information regarding the above listed protocol. This information included data requested by the IRB and recently submitted by investigators involved in this study. The committee has also examined the web sites for Bio-Energy Services.

Upon review of this data at the June 5, 2002, meeting of the IRB, the committee unanimously voted to terminate approval for Protocol BDS PAP001 for all investigators. The reasons for this termination include:

- Noncompliance in reporting serious adverse events to the IRB (Initial IRB Approval Notification dated May 24, 2001)
- Noncompliance in adhering to the conditions set forth in the Informed Consent document [21 CFR 50.25(b)(3)]
- Making misleading claims on the web site regarding the device [21CFR 812.7]
- Commercialization of an investigational device [21CFR 812.7]
- Use of an investigational device outside the research arena [21CFR 812.7]
- Use of material unapproved by the IRB on the web site for subject recruitment (21CFR 812.7)
- Selection of subjects is inequitable in that subjects were dropped from the study when they lost the ability to pay for the visits [21CFR 56.111]

Effective immediately, all research activity with this device must cease [21CFR 56.103(a)]. In addition, you must remove the unapproved web site from the internet immediately.

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As the sponsor, you are responsible for terminating the study at all approved sites. You are also responsible for the return or disposal of all study devices [21CFR812.7(e)].

If you have further questions regarding this issue, please feel free to contact our office.

Sincerely,

Edward Juskelis, M.D.
IRB Medical Chairman

copy: Mr. John Isele, CDHR/FDA