

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
New Orleans District Office: 6600 Plaza Drive, Suite 400
New Orleans, LA 70127; Phone: 504/253-4500

Nashville Branch: 297 Plus Park Blvd, Nashville TN 37217
615/781-5385

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED

PERIOD OF INSPECTION
3/5/01-5/10/01

C.F. NUMBER

TO: Meredith Rigdon Lentz, M.D.

TITLE OF INDIVIDUAL
Sponsor and Principal Investigator

TYPE ESTABLISHMENT INSPECTED
Sponsor & Clinical Investigator

FIRM NAME
Lentz Apheresis Center

NAME OF FIRM, BRANCH OR UNIT INSPECTED
same

STREET ADDRESS
397 Wallace Rd, Suite 314

STREET ADDRESS OF PREMISES INSPECTED
same

CITY AND STATE (Zip Code)
Nashville, TN 37211

CITY AND STATE (Zip Code)
same

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

DEVICE STUDIES

1. The PI (who is also the sponsor) conducted investigational "studies" (using investigational devices) that did not have FDA/IRB knowledge of/approval. Patients signed "consents" to participate in these unapproved studies. The consents referenced that the patients' medical records "may be reviewed by the U.S. Food and Drug Administration and other government regulatory agencies". Examples of the unapproved studies/consents include:

(b) (4)

The consents lacked a contact person/phone number to call for questions regarding subjects' rights. Moreover, for the "column study", the column was "put together" on site by the sponsor. At least ^{(b)(4)} patients have received multiple procedures/treatment courses with the column.

2. The sponsor failed to assure that the trials were conducted per the protocols as submitted to FDA and per the regulations for the three IDE studies (b) (4). The sponsor failed to report to FDA non-compliance with the regulations/protocols.

According to Dr. Lentz, none of the subjects enrolled in the three IDE studies were registered at the (b) (4) as per protocol.

3. No monitoring of the three IDE trials was conducted.

4. The PI failed to report all deaths/adverse events that occurred during the studies. For example, (b) (4) subjects that was reported to FDA as participating in the colorectal cancer trial (b) (4) arrested immediately following her apheresis procedure on 10/26/99. The death was not reported to FDA. As this study had not been submitted to an IRB for review, the death was not reported to an IRB.

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EMPLOYEE(S) SIGNATURE

Patricia S. Smith

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Patricia S. Smith, Investigator

DATE ISSUED
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5. The sponsor has no written procedures for study monitoring or data handling for any of the studies.
6. The PI failed to maintain all submissions to/correspondence with the IRB.
7. Patients that were reported to FDA as subjects in the three IDE trials also participated in other concurrent studies (as in #1 above). Their participation was not reported to FDA.
8. At least two studies were submitted to the IRB for review/approval 1/22/96 prior to FDA approval for the study to proceed. One study, (b) (4)

(b) (4) was disapproved by FDA, per 1/17/96 letter; yet this study was submitted to the IRB 1/22/96 without an approved IDE. There is no documentation that the Board was informed of FDA's disapproval to conduct the study/lack of IDE or that the PI had withdrawn the protocol 2/16/96 from his IDE submission. The 4/13/00 Metastatic Cancer study progress report/request for renewal submitted to the IRB states (b) (4) subjects were enrolled in this study.

The protocol, (b) (4)

(b) (4)

(b) (4) was submitted to the Board 1/22/96-- prior to receiving FDA's conditional approval 3/1/96 to proceed with the study. No documentation was observed that the Board was informed of this conditional approval to proceed.

9. Two IDE studies were conducted without IRB review/approval. These are: (b) (4)
(b) (4); and
(b) (4).

10. No case report forms or study subject rosters were completed for the colorectal cancer study (b) (4) or breast cancer study (b) (4) above. A subject roster was not maintained for the melanoma study. During the inspection, subject rosters for the three IDE studies were generated per FDA request. Only limited case report forms were filled out for the melanoma study (covered up to (b) (4) procedures even though several additional procedures were performed on the study subjects). These forms were not filled out concurrent with study activities—they were filled out after the fact in 1999 even though the study began in 1996. No case report form was observed for one of the subjects as reported to FDA (on the generated roster). A case report form was observed for patient (b) (7)(C) yet this patient is not listed on that study roster.

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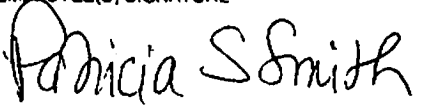
EMPLOYEE(S) SIGNATURE

Patricia S Smith

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Patricia S. Smith, Investigator

DATE ISSUED
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CITY AND STATE (Zip Code) Nashville, TN 37211		STREET ADDRESS OF PREMISES INSPECTED same	
		CITY AND STATE (Zip Code) same	
DURING AN INSPECTION OF YOUR FIRM I OBSERVED:			
<p>11. Numbers of treated/enrolled subjects and their names do not match what was reported to FDA as compared to what was reported to the IRB. FDA approved two "humanitarian exemptions" for the melanoma study (b) (4) —patients (b) (7)(C). The PI reported to the IRB, however, that patients (b) (7)(C) were the FDA approved exemptions-- but for the Metastatic Cancer study (the study that never received FDA approval/approved IDE). The patient (b) (7)(C) signed a consent 6/12/96—before the exemption was granted per 6/13/96 FDA letter. Moreover, the PI signed this consent 6/11/96-- prior to the patient's signature. Per PI's 7/26/96 letter to FDA, he reports only one of the two exemptions was enrolled (b) (7)(C). Patient (b) (7)(C) was reported as "never enrolled", as her disease progressed beyond the restrictions as stated in the protocol.</p> <p>In addition, numbers of patients treated exceeded the FDA-approved enrollment. For example, only (b) (4) patients could be enrolled in the breast cancer trial (b) (4) yet the site reported data for (b) (4) subjects. And, as indicated earlier, patient (b) (7)(C) signed a consent to participate in the melanoma study; a limited case report form was completed for this patient—but his name is not on the generated list of subjects for this study. Per PI, he treated patients "off-study" with the investigational device.</p> <p>12. None of the consents observed met FDA specific IDE provisions for the specific study/IDE as applicable. The consents for the unapproved studies lack a contact person for subjects to call regarding subjects' rights. None of the consents are specific for the costs incurred by the patients. For the (b) (4) patients signed a "RELEASE AND COVENANT NOT TO SUE" and were asked to, (b) (4)</p> <p>Only (b) (4) of the reported (b) (4) subjects enrolled in the breast cancer study (b) (4) signed a consent for "metastatic breast cancer". This consent does not mention IRB review or list a contact for questions regarding subjects' rights. In addition, it promises confidentiality and that the subject "will never be identified by name in any report". The PI failed to make FDA-required corrections to the consent and add, for example, "potential adverse event" such as "iatrogenic anemia" to the consent, per 6/3/99 and 8/17/99 letters. No documentation of this change was observed, as none of the breast cancer subjects signed the consent as per the IDE.</p> <p>None of the (b) (4) reported subjects for the colorectal cancer study signed the consent as per IDE (b) (4). Per 12/30/97 FDA letter, Dr. Lentz was informed of the required changes to be made to the informed consent. No documentation of changes was observed, as again, the subjects in this study (colorectal cancer) did not sign such a consent.</p>			
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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:			
<p>13. Consents to participate in the studies were often obtained after the vascular catheter had been surgically placed in preparation for the apheresis procedures.</p>			
<p>14. Records show a discrepancy as to the identity of the sponsor of the investigational device studies. Per submissions to FDA, Dr. Meredith Rigdon Lentz is identified as the sponsor and as the Principal Investigator. Some records submitted to the IRB report the sponsor to be (b) (4) a company described by Lentz as the U.S. and foreign patent holder of the filtration device (manufactured by (b) (4) Lentz is identified as the "inventor and a stockholder in (b) (4) "—"the sponsor of the research in the US".</p>			
<p>15. The PI failed to maintain adequate test article accountability records. No records were observed of the PI's purchase/receipt of the pheresis machines. Moreover, invoices covering shipment of the filters/blood tubing sets were dated Dec., 1998 through 2000. No earlier invoices were observed covering the period from study initiation in mid-1996 to late 1998. In addition, per invoices, the filters received by Dr. Lentz were (b) (4) No documentation was observed of FDA notification/approval of the filter change.</p>			
<p>16. No documentation was observed of IRB review/approval of any "educational material" that was provided to the patients/prospective subjects or Dr. Lentz' web site that described his research activities.</p>			
<p>II. MELANOMA STUDY (b) (4)</p>			
<p>A. Protocol Deviations</p>			
<p>1. Subjects received concurrent chemotherapy and/or radiation. These therapies were not reported in the CRF's. For example, Subject (b) (7)(C) was being apheresed from 6/18/97 through 8/15/97; yet received "a course of palliative irradiation" from 8/6-20/97. Subject (b) (7)(C) also participated in the "Biomodulation" study 1/26/99. (He received 14 treatments from Jan. 26 through Feb. 12, 1999.) He again signed the "Biomodulation" consent 6/8/99. He received 10 treatments from June 8-21, 1999. This subject also received radiation treatments 6/21/99 - 7/9/99.</p> <p>-Subject (b) (7)(C) was initially apheresed 10/16/97-11/7/97 (17 procedures). He was receiving concurrent chemotherapy. He received 19 additional procedures 4/7/98 through 5/1/98.</p>			
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Nashville, TN 37211	same	

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

-Subject ^{(b) (7)(C)} was initially apheresed 8/25/98- 9/15/98 (15 procedures). She also received concurrent chemotherapy during the apheresis procedures. This is true for the nine procedures she received 12/1-14/98; the 8 procedures of 2/9-18/99, and the nine procedures of 10/19-29/99. She signed the "Biomodulation" study consent 10/18/99 and 1/18/00.

-Subject ^{(b) (7)(C)} received ^{(b) (4)} during his initial procedures of 10/21/97 - 11/7/97. He participated in the "Biomodulation" study, and he signed that consent 10/11/99.

- Subject ^{(b) (7)(C)} began apheresis less than 21 days post ^{(b) (4)} as did Subjects ^{(b) (7)(C)}
- Subject ^{(b) (7)(C)} was enrolled with a WBC of ^{(b) (4)} (per protocol should be greater than ^{(b) (4)}).
- Subject ^{(b) (7)(C)} was enrolled with a lesion in a site that had previously received radiation (pelvis). This was also seen for Subject ^{(b) (7)(C)} who had new lesions in the axilla where he had previously received radiation therapy.
- Subject ^{(b) (7)(C)} only received 4 apheresis treatments.
- Subject ^{(b) (7)(C)}, who was from outside of the U.S., did not have any documentation of scans done here (PI's site) pre or post treatment. The patient arrived with records. His file contained no additional scans.
- Subject ^{(b) (7)(C)} was enrolled without having failed any previous therapies such as chemotherapy, ^{(b) (4)}. This was seen for Subject ^{(b) (7)(C)} also.

B. Consent Deviations

- On 6/13/96 FDA approved the inclusion of two subjects that failed to meet study inclusion provided that the PI amend the consent and obtain IRB approval of the amended consent. No documentation was observed of IRB review/approval of an amended consent. Moreover, the consent submitted to FDA and signed by Subject ^{(b) (7)(C)} and dated 6/12/96 entitled, ^{(b) (4)} with a revision date of 5/15/96 was not observed in the subject's file. The signed consent in the subject's medical file was the "Metastatic Melanoma" consent with the words "Metastatic Melanoma MEL 1" marked through and "Adenocarcinoma" written in above. This consent signature page does not bear the revision date of 5/15/96.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Patricia S Smith</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Patricia S. Smith, Investigator	DATE ISSUED 5/10/01
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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:			
<p>2. No signed informed consent was observed in the files for Subject (b) (7)(C) who began treatment 12/18/96; and Subject (b) (7)(C) (who flew in from (b) (7)(C)). His initial procedure was 12/2/97.</p> <p>-No signed informed consents were observed for Subject (b) (7)(C) who received apheresis treatments 10/21/97 -11/7/97; and fifteen procedures beginning 4/6/98. He did not sign the melanoma study consent until 6/5/98 for procedures that began at that time.</p> <p>3. The PI signed the informed consent 9/15/97—a day prior to the date the subject (b) (7)(C) signed on 9/16/97. Moreover, the port placement was on 9/15/97—prior to the subject's consent.</p> <p>C. Reporting Discrepancies</p> <p>1. According to the final report submitted to the IRB dated 12/9/98, this site enrolled a total of (b) (4) subjects—(b) (4) per roster generated during the inspection, however, two females were enrolled (b) (7)(C). It appears that patient (b) (7)(C) was included in this "final report"; yet Subject (b) (7)(C) was not. In addition, there is no mention in this report of the two "humanitarian exemptions".</p> <p>2. As noted earlier, not all adverse events were reported to FDA/the IRB. Subject (b) (7)(C) was noted to have experienced a seizure while being apheresed; however no documentation was observed that this event was reported to the IRB.</p> <p>3. No documentation was observed of the PI's notification to FDA or the IRB of his elimination of co-investigators. When the study was initially submitted to and reviewed by the IRB in 1996, three co-investigators were identified. Lentz at that time was employed in the same group practice as the three co-investigators. When the PI formed his own practice 8/1/97, the three co-investigators were no longer a part of the study. His submission to the IRB dated 8/8/97 includes a revised protocol that still lists the three co-investigators. His 8/29/97 progress report to the IRB identifies two "Associate Investigators".</p> <p>4. Subjects received multiple treatments/longer courses that were not reported to FDA and/or IRB. For example, Subject (b) (7)(C) initial apheresis course of 12 treatments was from 1/27/97 - 2/21/97. The subject returned for an additional "course" from 6/18/97 through 8/15/97—31 procedures. From his study entry to 8/15/97 he was treated 43 times. He again signed the melanoma study consent 11/17/98 (treated 20 times from 11/18/98 - 12/18/98) and signed a longer consent version 6/8/99.</p>			
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DURING AN INSPECTION OF YOUR FIRM I OBSERVED: <p style="margin-top: 20px;">-Subject ^{(b) (7)(C)} received 12 apheresis procedures 3/7/97 - 4/7/97 and an additional 23 from 6/19/97- 8/1/97.</p> <p>5. No documentation was observed of the submission to the IRB or the IRB's review/approval of enrollment of the two patients that did not meet protocol inclusion.</p> <p>6. The PI failed to submit to the IRB progress reports at the required intervals, thus allowing IRB approval to expire. For example, the study was initially approved 2/6/96 for six months. Progress report/request for renewal was not submitted until 8/26/96. Re-approval for another year was not granted until 10/2/96. The next progress report was not submitted until 8/29/97, with re-approval for another year granted 11/4/97. Final report was submitted to the Board 12/9/98.</p> <p>III. BREAST CANCER STUDY (b) (4)</p> <p>A. Protocol Deviations</p> <p>1. Files for ^{(b) (4)} of the ^{(b) (4)} enrolled subjects lacked documentation of biopsy-proven diagnosis of "infiltrating ductal breast cancer" as per protocol inclusion eligibility criteria.</p> <p>2. At least ^{(b) (4)} Subjects (b) (7)(C) of the ^{(b) (4)} reported subjects enrolled also received chemotherapy and/or other therapies (such as (b) (4) concurrent with the apheresis procedures. These other therapies were not reported to FDA.</p> <p>3. Subject ^{(b) (7)(C)} was enrolled even though she was ineligible as per protocol (tumor /s in sites of previous radiation therapy). Subject ^{(b) (7)(C)} was ineligible as per protocol (tumor in CNS).</p> <p>B. Consent Deviations</p> <p>1. As stated earlier, none of the ^{(b) (4)} enrolled subjects signed the consent as per the IDE. Subject ^{(b) (7)(C)} signed the "Unblocking" consent 11/1/99 and a different (unapproved) metastatic breast cancer consent 1/24/00. Subject ^{(b) (7)(C)} signed this same unapproved consent 2/17/98. Subject ^{(b) (7)(C)} signed that consent 2/9/98; as did Subject ^{(b) (7)(C)} on 4/20/98.</p> <p>-Subject ^{(b) (7)(C)} signed the "Unblocking" consent 11/1/99 and 5/22/00; and the "Biomodulation" consent 3/20/00.</p> <p>-Subject ^{(b) (7)(C)} signed the "Unblocking" consent 10/27/99.</p>			
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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

C. Reporting Discrepancies

1. Subjects received multiple procedures/courses that were not reported to FDA. For example, Subject (b) (7)(C) received 15 treatments during her first cycle beginning 11/2/99. She received a second cycle consisting of 15 procedures from 1/25/00 - 2/15/00.

-Subject (b) (7)(C) completed 17 procedures during cycle #1 (2/17/98-3/11/98) and 9 procedures during cycle #2 (4/22/98 - 5/4/98).

-Subject (b) (7)(C) received thirteen procedures during her first cycle 2/10-26/98; eight during her second cycle 3/24/98- 4/3/98; and one procedure during her third cycle beginning 5/5/98. Ten minutes into the procedure on 5/5/98, the patient was unresponsive and "appeared to be seizing". CPR was started but the patient arrested. Report to FDA did not indicate the patient arrested during the procedure. Since this study was not reviewed by an IRB, the death was not reported to an IRB.

-Subject (b) (7)(C) received 15 treatments during cycle #1 (11/2-22/99); 5 treatments in March, 2000; 5 treatments in May, 2000.

-Subject (b) (7)(C) received 15 procedures 4/21/98 - 5/15/98; and 10 procedures beginning 6/30/98.

III. COLORECTAL CANCER STUDY (b) (4)

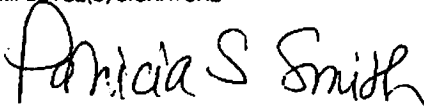
A. Protocol Deviations

- 1) All (b) (4) subjects received concurrent chemotherapy with their apheresis procedures. The concurrent therapies were not reported to FDA.
- 2) Of the (b) (4) reported subjects enrolled in this study, Subject (b) (7)(C) began apheresis 1/20/98; yet had received radiation through 1/7/98—not a minimum of 21 days as per protocol.

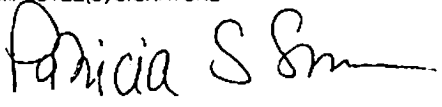
B. Consent Deviations

1. As stated earlier, none of the 4 enrolled subjects signed a consent to participate in the IDE study entitled. (b) (4)

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	(b) (4)		

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		CITY AND STATE (Zip Code) same	
DURING AN INSPECTION OF YOUR FIRM I OBSERVED:			
<p>-When subject (b) (7)(C) was enrolled in this study, he signed a consent 1/20/98 to participate in the "Immune Unblocking" study. His "vas cath" was placed 1/19/98--prior to the consent. He signed a second "Unblocking" consent 3/9/98 for his second cycle of apheresis.</p> <p>-Subject (b) (7)(C) signed a consent for a "Metastatic GI Cancer" study 2/2/99 and completed 15 procedures. He completed an additional 9 procedures in March, 1999 after signing the "Biomodulation" study consent and the "Metastatic Cancer" study consent 3/16/99. He signed the "Unblocking" study consent 7/7/99 and completed 15 additional procedures. On 10/4/99 he signed the "Biomodulation" study consent and completed 18 additional apheresis procedures.</p> <p>-Subject (b) (7)(C) signed the "Unblocking" study consent 1/6/98. He completed 15 procedures.</p> <p>-Subject (b) (7)(C) signed the "Unblocking" study consent 3/16/99; although her vas cath was placed 3/15/99--prior to her consent. She completed 15 procedures by 4/99. She signed the "Biomodulation" study consent 5/4/99. She completed 13 procedures. She signed the "Metastatic Cancer" study consent 7/19/99 and completed 10 procedures. She again signed the "Metastatic Cancer" consent 10/11/99. As her ninth procedure on 10/26/99 was finishing, she became unresponsive and expired in the emergency room. As stated earlier, this death was not reported to FDA nor was it reported to an IRB, as the study had not been submitted to an IRB for review.</p> <p>The multiple courses of treatments were not reported to FDA.</p> <p><u>DRUG STUDIES</u></p> <p>1. The PI conducted investigational drug studies without documentation of FDA and/or IRB approval. Examples include:</p> <p>(b) (4) (b) (4) There is no documentation that the drug manufacturer (b) (4) who provided the drug for another (b) (4) "Investigator IND study" that Lentz was conducting) was aware of this "new protocol" and approved the use of the test article in the new study. Per (b) (4) 4/13/98 Investigator IND Letter of Agreement, the PI signed and agreed "to use any drug provided by (b) (4) under this Investigator IND exclusively as proposed in the Investigator IND protocol" submitted to (b) (4) and FDA. Study drug, therefore, was to be used for the IND protocol only.</p>			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Patricia S. Smith, Investigator
		DATE ISSUED 5/10/01	

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER New Orleans District Office: 6600 Plaza Drive, Suite 400 New Orleans, LA 70127; Phone: 504/253-4500 Nashville Branch: 297 Plus Park Blvd, Nashville TN 37217 615/781-5385	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED to: Meredith Rigdon Lentz, M.D.		PERIOD OF INSPECTION 3/5/01-5/10/01	C.F. NUMBER
TITLE OF INDIVIDUAL Sponsor and Principal Investigator		TYPE ESTABLISHMENT INSPECTED Sponsor & Clinical Investigator	
FIRM NAME Lentz Apheresis Center		NAME OF FIRM, BRANCH OR UNIT INSPECTED same	
STREET ADDRESS 397 Wallace Rd, Suite 314		STREET ADDRESS OF PREMISES INSPECTED same	
CITY AND STATE (Zip Code) Nashville, TN 37211		CITY AND STATE (Zip Code) same	
DURING AN INSPECTION OF YOUR FIRM I OBSERVED:			
<p>-Treatment <u>(b) (4)</u> No documentation was observed of IRB approval of Dr. Lentz as sponsor and Principal Investigator. A Board in <u>(b) (4)</u> approved <u>(b) (7)(C)</u> to be PI and Dr. Lentz to be sponsor. FDA, however, stated that it was not appropriate for the patient's family member to be the PI/treating physician. Dr. Lentz then agreed to be the PI; however, no Board approval of this change was observed. Dr. Lentz was not the treating physician—<u>(b) (7)(C)</u> was. The test article was shipped directly from <u>(b) (4)</u> to <u>(b) (7)(C)</u> yet no signed <u>(b) (4)</u> identifying <u>(b) (7)(C)</u> as subinvestigator was observed nor was documentation of <u>(b) (7)(C)</u> approval by an IRB to be a sub-investigator for Dr. Lentz as PI.</p> <p>2. Dr. Lentz failed to assure that the trials were conducted per the protocols as submitted to FDA and per the regulations. The studies include: <u>(b) (4)</u> under <u>(b) (4)</u>; and the above Treatment <u>(b) (4)</u> <u>(b) (4)</u></p> <p>3. No monitoring of the <u>(b) (4)</u> studies has been conducted. Inadequate recordkeeping was observed of test article accountability. No documentation was observed of disposition of test article that was returned by patients/patients' families. No study case report forms were observed.</p> <p>4. No documentation was observed that Dr. Lentz informed <u>(b) (4)</u> in his initial submission to <u>(b) (4)</u> that the study under <u>(b) (4)</u> had been disapproved by his local IRB.</p> <p>5. Dr. Lentz failed to maintain all submissions to and correspondence with <u>(b) (4)</u></p> <p>6. Dr. Lentz failed to report to FDA all adverse events.</p> <p>7. "Subjects" that Dr. Lentz never saw were enrolled in the <u>(b) (4)</u> studies. Consents were faxed to the patients' physicians. The patients signed the consents that were then faxed back to Dr. Lentz. These patients were never seen in Lentz' clinic. The patients' local physicians were never identified/approved as subinvestigators.</p> <p>8. "Subjects" signed consents for the <u>(b) (4)</u> <u>(b) (4)</u> study that were not the IRB-approved version. At least four subjects signed consents that referenced a local IRB Chairman <u>(b) (7)(C)</u> and his phone number. His Board disapproved this study. Patient JLC (who has prostate cancer) signed a consent 6/21/00. His consent references <u>(b) (7)(C)</u> Two patients signed consents with the title,</p>			
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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:			
<p> (b) (4) Patient (b) (7)(C) signed it 10/9/98; and Patient (b) (7)(C) signed it 8/3/98. The consent references (b) (7)(C) as the contact regarding subjects' rights or questions about the research. </p> <p> One patient (b) (7)(C) signed a consent 6/17/98 with the title (b) (4) (b) (4). The consent also references (b) (7)(C) </p> <p> The above four consents state that (b) (4) is approved in the U.S. It did not receive FDA approval (for one use, leprosy) until 7/98. </p> <p> I. Failure to Follow the Protocol </p> <ol style="list-style-type: none"> Per protocol and informed consent for the (b) (4) study under (b) (4) the subjects were to be "seen by the study doctor every two weeks for twelve months". As stated earlier, some patients were never seen in Lentz' clinic or by Dr. Lentz. The other patients were not seen on a biweekly basis as per protocol. Documentation was not observed that all female subjects of childbearing potential had pregnancy tests performed at the protocol stated intervals—pre (b) (4) initiation, 9 to 10 days after receiving the initial dose, and once a month (if menstrual cycle is regular—more frequently if menstrual cycle is irregular). 			
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