IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

NOV 02 1999

MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

UNITED STATES OF AMERICA, Plaintiff, v. ABBOTT LABORATORIES, a corporation, and MILES D. WHITE, and THOMAS D. BROWN individuals, Defendants.	)	Civil Action No. 99C 713 JUDGE LEINENWEBER MAGISTRATE JUDGE SCHENKIER CONSENT DECREE OF PERMANENT INJUNCTION

The United States of America, plaintiff, having filed a Complaint for Injunction against Abbott Laboratories, a corporation, and Miles D. White, Chief Executive Officer, Abbott Laboratories, and Thomas D. Brown, President, Abbott Diagnostics Division, individuals, and defendants having appeared and having consented to entry of this Decree without contest, without admitting the allegations of the Complaint, and before any testimony has been taken, and the United States of America having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter herein, and has personal jurisdiction over all parties to this action pursuant to 21 U.S.C. § 332(a), 28 U.S.C. §§ 1331, 1337, and 1345, and 42 U.S.C. §§ 262 and 264.

2. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c).

3. The Complaint for Injunction states a cause of action against the defendants under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.* and the Public Health Service Act (PHSA), 42 U.S.C. §§ 201 *et seq.*

4. Except as provided in paragraph 5 of this Decree, the defendants, Abbott Laboratories (Abbott), a corporation, and Miles D. White, Chief Executive Officer, Abbott, and Thomas D. Brown, President, Abbott Diagnostics Division, individuals, while they are officers or employees of Abbott or any Abbott subsidiary, affiliate, or successor entity, and each and all of Abbott's officers, agents, employees, representatives, and attorneys, and those persons in active concert or participation with any of the defendants, are permanently enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing *in vitro* diagnostic devices, including finished devices, accessories, and components, at Abbott's device manufacturing facilities located at 100/200 Abbott Park Road, Abbott Park, Illinois (Abbott Park), and at Route 41 & Martin Luther King Drive, North Chicago, Illinois (K2), unless and until:

A. Defendants select an independent person or persons (the "expert(s)") to make inspections of Abbott's device manufacturing facilities at Abbott Park and K2 to determine whether the methods, facilities, and controls are operated and administered in conformity with the Quality System Regulation, 21 C.F.R. Part 820. The expert(s) shall be qualified by education,

training and experience to conduct such inspections, and shall be without former or current personal or financial ties (other than consulting agreements between the parties) to the defendants or their immediate families; and

B. The expert(s) inspects Abbott's device manufacturing facilities and manner of operation at Abbott Park and K2, and certifies in writing to FDA that Abbott's corrective and preventive action (CAPA) system is in conformity with the Quality System Regulation; and the defendants report in writing to FDA the actions they have taken to bring Abbott's CAPA system into conformity with the Quality System Regulation since the May through July 1999 inspection. Within twenty (20) days after FDA receives the expert(s)'s certification and defendants' report, FDA representatives, may, in their discretion, commence an inspection of Abbott's facilities at Abbott Park and K2 and undertake such additional examination and analyses (as provided in paragraphs 20 and 21) as they, in consultation with FDA's Office of Compliance, Center for Devices and Radiological Health, and FDA's Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, deem appropriate to determine whether Abbott's CAPA system is in conformity with the Quality System Regulation; and

C. Within forty-five (45) days after FDA has completed its inspection, or, if no inspection is conducted, within forty-five (45) days after receipt of the expert(s)'s certification and defendants' report, FDA advises the defendants in writing that

Abbott's CAPA system is in conformity with the Quality System Regulation; and

D. After defendants have brought all of the devices listed in paragraph 5(A) into conformity with the Quality System Regulation (except that B12, Folate, Ferritin, Hepatitis HBe/Anti HBe, and HCG (testpack) may be brought into conformity with the Quality System Regulation concurrently with those products listed in paragraph 5(A), in accordance with paragraphs 7 and 8), the expert(s) certifies in writing to FDA that the manufacturing processes for a product group not covered by paragraph 5(A) have been validated and that the products and processes that have been certified are in conformity with the Quality System Regulation. Within five (5) working days after FDA receives the expert(s)'s certification, FDA may request any certified validation package(s) that the agency wishes to review. FDA may inspect Abbott's facilities at Abbott Park and K2 after receiving the expert(s)'s certification to determine whether those products and the processes for those products are in conformity with the Quality System Regulation; and

E. FDA notifies the defendants in writing, for each group of products it has reviewed, that the group appears to be in compliance with the Quality System Regulation and may be distributed. FDA will provide such notice (if appropriate) within sixty (60) days of completing any inspection pursuant to paragraph 4(D), or if no inspection is undertaken, within sixty (60) days of receiving validation package(s) requested by FDA

pursuant to paragraph 4(D), or if no validation package(s) is requested and no inspection is undertaken, within ten (10) working days of receiving the expert(s)'s certification pursuant to paragraph 4(D);

F. To enable users to standardize or obtain alternative test methods, the injunctive provisions of paragraph 4 shall not take effect until 30 days after the date of entry of this Decree.

5. The injunctive provisions set forth in paragraph 4 shall not prohibit the defendants from:

A. Manufacturing, processing, packing, labeling, holding, and distributing the following products, including their necessary accessories, components, calibrators and controls, the continued availability of which FDA currently believes to be medically necessary:

1. AFP;
2. Anti-Delta;
3. Amikacin;
4. Ausab;
5. Auszyme Monoclonal;
6. Beta 2 Microglobulin;
7. CA 125;
8. CA 15-3;
9. Carbamazepine/Free Carbamazepine;
10. CEA;
11. Chlamydia (LCx probe only);

12. CK-MB;

13. CMV (IGG, IGM);

14. CMV Total AB EIA;

15. Corzyme;

16. Cyclosporine;

17. Digitoxin;

18. Digoxin II;

19. Drugs of Abuse/Toxicology Panel;

20. Estriol/Free Estriol, FSH, LH, Progesterone, Estradiol, Prolactin;

21. Fetal Lung Maturity II;

22. Gentamicin;

23. Glycated Hemoglobin;

24. Gonorrhea (LCx probe only);

25. HAVAB;

26. HAVAB-M;

27. HBsAg Confirmatory Test for Auszyme Monoclonal;

28. HCG (not testpack);

29. HCV EIA 2.0;

30. HIVAB HIV-1/HIV-2 (rDNA) EIA;

31. HTLV-I/HTLV-II EIA;

32. HIVAG-1 Monoclonal;

33. HIVAG-1 Monoclonal Blocking Antibody;

34. Hepatitis B Core IGM;

35. Homocysteine;

36. Methotrexate;

37. Myoglobin;

38. N-Acetylprocainamide;

39. PAP assay;

40. Phenobarbital;

41. Phenytoin/Free Phenytoin;

42. Procainamide;

43. Quinidine;

44. Rubella (IGG, IGM);

45. Tacrolimus;

46. Theophylline;

47. Thyroid Panel (TSH, T3, T4, Free T3, Free T4, T Uptake);

48. Tobramycin;

49. Total b-HCG;

50. Total PSA;

51. Toxoplasmosis (IGG, IGA, IGM);

52. Troponin;

53. Valproic Acid/Free Valproic Acid;

54. Vancomycin;

B. After providing written notice to FDA that Abbott intends to do so, and unless FDA objects within five (5) working days after receiving such notice, manufacturing, processing, packing, labeling, holding and shipping limited quantities of devices for the sole purpose of validating the processes and systems associated with the manufacturing, processing, packing, labeling, or holding of *in vitro* diagnostic devices;

C. Manufacturing, processing, packing, labeling,

holding, and exporting any *in vitro* diagnostic device, including finished devices, accessories, components, calibrators, and controls, in compliance with 21 U.S.C. § 381(e) or § 382, as appropriate. CA19-9 may be exported in accordance with the procedures set forth in 21 U.S.C. § 381(e). Partially processed biological products not intended for sale in the United States and intended for manufacturing into finished products outside the United States may be exported solely for further manufacturing into viral marker test kits not intended for reimportation into the United States. These products must be labeled on the outside of the shipping package that they are intended for export only. Prior to export, defendants shall notify the appropriate public health authorities in the countries to which these partially processed biological products are intended to be exported that these products shall not be reimported into the United States and that FDA has alleged that the methods used in, and the facilities and controls used for, their manufacture, processing, packing and holding are not in conformity with current good manufacturing practice. Defendants shall provide a copy of this Decree to the appropriate public health authorities in these countries as part of such notice. Defendants shall maintain records documenting the export of such partially processed biological products. Records shall be kept identifying the manner in which the defendants complied with the notification requirements described in this paragraph. All of these records shall be made immediately available for FDA inspection on request;

D. Distributing, at K2, finished devices and unopened accessories, components, and materials that are completely manufactured, processed, packed, and labeled at facilities other than Abbott Park or K2;

E. Manufacturing, processing, packing, labeling, holding, and distributing limited quantities of devices, including their necessary accessories, components, calibrators, and controls, for the sole purpose of conducting clinical investigations in accordance with the FDCA, as long as Abbott obtains written agreement from the recipient(s) that the product is for investigational use only.

6. In recognition of the government's right to seek monetary equitable relief for the distribution of medically necessary *in vitro* diagnostic devices that the government alleges were not manufactured in compliance with the Quality System Regulation, but without admitting that allegation or any violation of the law, Abbott agrees to pay to the United States Treasury, within ten (10) days of the date of entry of this Decree, the amount of one hundred million dollars ($100,000,000).

In addition, for each product listed in paragraph 5(A) that FDA has determined has not been brought into conformity with the Quality System Regulation within three hundred and sixty-five (365) days after the date of entry of this Decree and which Abbott continues to sell after such date, Abbott shall, at the end of every ninety (90) day period following three hundred and sixty-five (365) days after the date of entry of this Decree, pay

to the United States Treasury an amount equal to sixteen percent (16 ⅔) of the gross revenue generated by the sale of such non-conforming product(s) in the United States, from and including the date on which such ninety (90) day period began, to but not including the date on which the certification of such conformity (as described in paragraph 9) is received by FDA, even if FDA does not determine that such conformity has been achieved until a later date; provided, however, that Abbott will increase its payments appropriately if FDA later determines that such compliance was not achieved until a later date. The amount(s) paid under this paragraph shall be determined by a qualified financial auditor, who shall be paid by Abbott, acceptable to Abbott and FDA, and without former or current personal or financial ties to the defendants or their immediate families. Abbott shall cooperate fully with the auditor and provide all records reasonably requested by the auditor to make the determination described in this paragraph.

The parties acknowledge that the payment(s) under this Decree are not a fine, penalty, forfeiture or payment in lieu thereof.

7. Within sixty (60) days after the date of entry of this Decree, defendants shall submit to FDA a proposed master compliance plan, a proposed validation plan and a proposed overall validation procedure for accomplishing validation of manufacturing processes affecting products covered by paragraphs 4 and 5 and for bringing defendants' processes used to

manufacture *in vitro* diagnostic products into conformity with the Quality System Regulation. The master compliance plan and validation plan shall: (a) identify the specific manufacturing processes to be validated and the products affected by such process(es); (b) include a proposed validation schedule; and (c) provide that Abbott's manufacturing processes for products listed in paragraph 5(A) shall be brought into conformity with the Quality System Regulation within three hundred and sixty-five (365) days after the date of entry of this Decree. FDA shall respond to defendants' proposed master compliance and validation plan and overall validation procedure within thirty (30) days of receipt. Abbott understands that it may be necessary for FDA to adjust the number of submissions that Abbott proposes to make within a period of time, to enable FDA to meet the time frames for review set forth in paragraph 8 of this Decree. After the schedule has been approved, FDA and Abbott may stipulate in writing to a revised schedule.

8. After Abbott's expert(s) has certified to FDA that a process(es) affecting any product listed in paragraph 5(A) has been validated and/or that a product(s) listed in paragraph 5(A) has been completely validated, FDA will determine, within sixty (60) days of receipt of the certification, whether the process(es) and/or product(s) have been validated and are in conformity with the Quality System Regulation on the basis of (in FDA's discretion) inspection, analyses, and/or review of all relevant records.

9. Abbott's expert(s) shall, if appropriate, certify to FDA that all processes affecting products listed in paragraph 5(A) have been brought into conformity with the Quality System Regulation. Within twenty (20) days after FDA receives the expert(s)'s certification, FDA may commence an inspection of Abbott's facilities at Abbott Park and K2 and undertake such additional examination and analyses (as provided in paragraphs 20 and 21) as it, in consultation with FDA's Office of Compliance, Center for Devices and Radiological Health, and FDA's Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, deems appropriate to determine whether the defendants' processes for products listed in paragraph 5(A) are in conformity with the Quality System Regulation; and within forty-five (45) days after FDA has completed its inspection, FDA will advise the defendants in writing whether Abbott's processes for products listed in paragraph 5(A) are in conformity with the Quality System Regulation.

10. During the first three hundred and sixty-five (365) days after the date of entry of this Decree, for each process identified pursuant to paragraph 7 that affects a product in paragraph 5(A), Abbott shall pay the sum of fifteen thousand dollars ($15,000) per process, per business day, for failure to accomplish an adequate validation, as determined by FDA, in accordance with the validation schedule approved under paragraph 7. During the same period, Abbott shall also pay fifteen thousand dollars ($15,000) per business day for failure to bring

the CAPA system into conformity with the Quality System Regulation as determined by FDA within one hundred and twenty (120) days after the date of entry of this Decree. For purposes of this paragraph, if Abbott submits to FDA the certification of the expert(s) that an adequate validation has been accomplished or that the CAPA system has been brought into conformity with the Quality System Regulation within the schedules under this Decree, no payment shall be imposed unless and until FDA notifies Abbott that such validation is not adequate or that the CAPA system is not in such conformity, in which case payment shall be due for each business day commencing on the day on which the action was due to be completed by Abbott. The total payments under this paragraph shall not exceed 10 million dollars ($10,000,000).

11. After entry of this Decree, FDA and defendants may, through a written joint stipulation, add products to paragraph 5(A).

12. The defendants shall destroy, at Abbott's expense and under FDA supervision, all finished *in vitro* diagnostic devices that, as of the 30th day after the date of entry of this Decree, are in Abbott's possession, custody, and control within the United States, and that were manufactured, processed (in any way), packed, or labeled at Abbott Park or K2, and all components that are in inventory at Abbott Park or K2; *except that*: (1) defendants need not destroy any product (or any component thereof) that falls within the terms of paragraph 5; and (2) defendants need not destroy any product (or any component

thereof) that falls within a group that FDA has approved under paragraph 4 if defendants submit to FDA a proposed reconditioning plan for the product or component, FDA in writing approves the plan, and FDA in writing finds the reconditioning to be satisfactory. No product (or any component thereof) in inventory need be destroyed if within thirty (30) days of any FDA request for such destruction defendants have sought judicial review as provided in paragraph 26, and until judicial review is complete and FDA's position has been upheld. FDA shall respond in writing to any proposed reconditioning plan within sixty (60) days of receipt.

13. After defendants have achieved compliance with paragraphs 4(A)-4(D) and FDA has notified them pursuant to paragraph 4(E), defendants shall retain an independent person or persons (the "auditor(s)") to conduct audit inspections of all *in vitro* diagnostic device manufacturing operations at Abbott Park and K2 no less than twice a year, for a period of four (4) years unless extended by FDA in writing. The auditor(s) shall be qualified by education, training and experience to conduct such inspections, and shall be without current or former personal or financial ties (other than the consulting agreements entered into by the parties) to the defendants or their immediate families and may, if defendants choose, be the same person described as the expert in paragraph 4(A) above.

14. At the conclusion of each audit inspection, the auditor(s) shall prepare a written audit report (the "audit

report") evaluating whether the defendants are in compliance with the Quality System Regulation, identifying any deviations from that regulation ("audit report findings"), and separately identifying those deviations that the auditor believes are significant. The auditor(s) shall provide a copy of the audit report in draft form to the defendants, so that they may comment on the findings. As part of every audit report except the first audit report, the auditor(s) shall assess the actions taken by defendants to correct all previous audit report findings. The final audit reports shall be delivered contemporaneously to FDA and the defendants by courier service or overnight delivery service. In addition, the final audit reports, drafts, and all of the defendants' comments on drafts, shall be maintained by Abbott in separate files at the Abbott Park and K2 facilities and shall be made immediately available for FDA inspection on request.

15. Defendants shall, within thirty (30) days of receipt of each audit report, correct any audit report findings, unless FDA notifies the defendants that a different time period is necessary. If, after receiving an audit report, defendants believe that correction of audit report findings will take longer than thirty (30) days, defendants shall, within ten (10) working days of receipt of the audit report, propose a schedule for completion of corrections ("correction schedule"), which must be approved by FDA prior to its implementation. FDA will notify the defendants of its decision regarding a proposed schedule

within ten (10) working days of receipt of the proposal. The time period for correction will not run during the time that FDA is reviewing defendants' proposed schedule. Defendants shall complete all corrections according to the approved correction schedule. Within twenty (20) days after the scheduled completion of the corrections, the auditor(s) shall review the actions taken by defendants to correct the audit report findings. Within five (5) working days of the completion of the auditor's review, the auditor shall report contemporaneously in writing to FDA and the defendants whether each of the audit report findings has been corrected.

16. Except as provided in paragraph 5, Abbott and each of the individual defendants, while they are officers or employees of Abbott or any Abbott subsidiary, affiliate, or successor entity, and each and all of Abbott's officers, agents, employees, representatives, and attorneys, and those persons in active concert or participation with any of the defendants, are permanently enjoined under 21 U.S.C. § 332(a) from directly or indirectly: introducing or delivering, or causing to be introduced or delivered, into interstate commerce any *in vitro* diagnostic device manufactured, processed, packed, held, labeled or distributed at Abbott Park or K2, including any component, part, or accessory of such device, that is adulterated within the meaning of 21 U.S.C. § 351(h); or causing the adulteration of any *in vitro* diagnostic device manufactured, processed, packed, held, labeled or distributed at Abbott Park or K2, while such device is

held for sale after shipment of one or more of its components in interstate commerce.

17. If at any time after this Decree has been entered, FDA determines that Abbott has failed, with respect to *in vitro* diagnostic products manufactured, processed, packed, held, labeled or distributed at Abbott Park or K2, to comply with the Quality System Regulation, any requirement of this Decree, the FDCA, the PHSA, or any regulation promulgated pursuant to the FDCA or the PHSA, or has failed to correct audit report findings under this Decree, within time frames specified by FDA, or, when no time frame has been specified, within thirty (30) days of receipt of an audit report, FDA may, as and when it deems necessary, order defendants in writing to take one or more of the following actions:

A. submit additional reports, notifications, or information to FDA and/or users;

B. submit any application or any supplement to an existing device or biological product application to FDA;

C. cease manufacturing, processing, packing, labeling, holding, and/or distributing any specified device(s), including any devices identified in paragraph 5;

D. recall, at Abbott's expense, any specified device(s), including any accessories and components;

E. take any action(s) authorized by the FDCA or the PHSA.

18. Any order issued pursuant to paragraph 17 shall be

issued by the Chicago District Director, the Director, Office of Compliance, Center for Devices and Radiological Health, or the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, as is appropriate, and shall specify the failures giving rise to the order. Unless a different time frame is specified by FDA, within five (5) working days after receiving an order pursuant to paragraph 17, defendants shall advise FDA in writing either that: (1) defendants are undertaking or have undertaken all corrective action(s) requested by FDA, in which event defendants shall also describe the specific action(s) taken or to be taken and the time frame(s) in which the action(s) will be completed; or (2) defendants do not agree with FDA's order. If defendants notify FDA that they do not agree with FDA's order, defendants shall explain in writing the reasons for their disagreement. FDA will review defendants' response and, in writing, affirm, modify, or withdraw its order as FDA deems appropriate. While defendants' response is under review by FDA, the order has no effect. After FDA review, unless FDA withdraws the order, FDA's order shall take effect as the final order. Immediately upon receipt of the final order, defendants shall proceed with implementation of all corrective action deemed necessary by FDA as set forth in the final order. Defendants shall continue to implement FDA's final order, unless and until FDA or the Court issues an order to the contrary.

19. If FDA orders a cessation of operations with respect to

specified device(s) under paragraph 17(C), defendants shall not resume manufacturing, processing, packing, labeling, holding, and/or distributing such devices until: (a) an expert(s) consultant certifies in writing to FDA that defendants have remedied the failure(s) upon which the cessation was based; (b) FDA inspects Abbott's facilities at Abbott Park and/or K2 to confirm the adequacy of the corrective action(s) (if it chooses to do so); and (c) FDA notifies defendants in writing (which FDA agrees to do within ten (10) days of receipt of the expert certification or within thirty (30) days after the completion of the FDA inspection, as applicable, if it believes such failures have been remedied), that defendants may resume manufacturing, processing, packing, labeling, holding, and/or distributing such devices. Any FDA inspections shall be conducted pursuant to paragraphs 20 and 21, and shall commence no later than twenty (20) working days after FDA's receipt of the expert(s)'s certification.

20. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Abbott's facilities at Abbott Park and K2, including buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Abbott's finished and unfinished materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, holding, and

distribution of any and all devices in order to ensure continuing compliance with the terms of this Decree. FDA shall provide Abbott with a receipt for any samples taken, and with copies of any photographs or recordings made. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the FDCA, 21 U.S.C. § 374.

21. Abbott shall pay the costs of all supervision, inspections, reviews, examinations, and analyses conducted pursuant to this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date of this Decree, these rates are: $57.08 per hour and fraction thereof per representative for inspection work; $68.42 per hour or fraction thereof per representative for analytical and review work; $0.31 per mile for travel expenses and $ 154.00 per day for subsistence expenses where necessary. FDA shall submit a detailed bill of costs to the General Counsel, Abbott, Department 364. In the event that the standard rates generally applicable to FDA supervision, inspection, review, examination or analysis are modified, these rates shall be increased or decreased without further order of the Court.

22. Within ten (10) days of the date of entry of this Decree, Abbott shall serve copies thereof upon each of its officers, and all persons who are in active concert or participation with Abbott's Diagnostics Division or the

defendants in the areas of manufacturing or quality systems for *in vitro* diagnostic devices. Also within ten (10) days, Abbott shall post a copy of this Decree on Abbott's intranet Web site in such manner to ensure that it will be viewed by all employees of Abbott's Diagnostics Division, and shall prominently post a copy of this Decree in the employee common areas in both the Abbott Park and K2 manufacturing facilities. Abbott shall ensure that the Decree remains posted on Abbott's intranet and in the employee common areas for a period of no less than six (6) months. Should any person become associated with Abbott subsequent to the periods described above who would have received a copy of this Decree had his/her association commenced before entry of this Decree, Abbott shall, within ten (10) days of the commencement of such association, serve a copy of this Decree on such person. Within thirty (30) days of the date of entry of this Decree, Abbott shall provide to FDA and to plaintiff's attorney an affidavit of compliance stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons upon whom this Decree has been served.

23. Abbott shall notify FDA within fifteen (15) days before any change in ownership or character of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the Abbott corporate structure or in the sale or assignment of any business assets,

such as buildings, equipment, or inventory, that may materially affect compliance with this Decree. Abbott shall provide a copy of this Decree to any potential successor or assignee before any sale or assignment.

24. Except as may otherwise be agreed to by FDA in writing, the defendants shall send via overnight mail or courier service all communications with FDA required under this Decree to: (1) Director, Chicago District Office, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606; (2) Director, Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, HFZ-300, 2098 Gaither Road, Rockville, Maryland 20850; and (3) Director, Office of Compliance and Biologics Quality, HFM-600, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200 N, Rockville, Maryland 20852-1448. All communications shall reference this civil action by case name and civil action number, and shall be sequentially numbered. Certifications under paragraph 4(D) and notices under paragraph 5(B) shall be sent by facsimile as well as by overnight mail or courier service.

25. Should the United States bring, and prevail in, a civil or criminal contempt action against any defendant(s) for a violation of the terms of this Decree, that defendant(s) shall pay attorneys' fees, travel expenses incurred by witnesses, court costs, expert witness fees, and analytical, review, and investigational expenses incurred in bringing such action.

26. All decisions conferred upon FDA in this Decree shall

be vested in the discretion of FDA, and, in the event of a decision adverse to defendants, shall include a written explanation of FDA's reasons. FDA's decisions shall be final and, unless explicitly provided elsewhere in this Decree, defendants shall abide by FDA's decisions unless revoked or modified by FDA or by this Court. If defendants seek judicial review, FDA's decisions shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Any such review of an FDA decision brought before this Court shall be based exclusively on the record before FDA at the time FDA made the decision at issue, and no discovery shall be taken by any party.

27. If defendants maintain a continuous state of compliance with this Decree and the Quality System Regulation for a period of five (5) years after the date of entry of this Decree and FDA has not notified the defendants that there has been a significant violation of this Decree or the Quality System Regulation during such time, the government will not oppose the defendants' petition to the Court to dissolve this Decree.

28. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this 2nd day of November, 1999.

UNITED STATES DISTRICT JUDGE

ENTRY CONSENTED TO:

Abbott Laboratories

by: Arthur N. Levine
Attorney for Abbott Laboratories and the individual defendants

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