Dear Colleague:

On November 2, 1999, the Department of Justice, on behalf of the Food and Drug Administration (FDA), entered into a consent decree of permanent injunction with Abbott Laboratories and responsible officials. This action involves the company's diagnostic devices division. We are writing to explain the significance of this action, and how it may affect the healthcare community.

Reason for seeking an injunction

We took this action because of the firm's long-standing failure to comply with FDA's Good Manufacturing Practices (GMP) regulation, now called the Quality System regulation, and its failure to fulfill commitments to correct deficiencies in its manufacturing operations.

These failures go back to 1993, when our inspection of the facilities where Abbott Diagnostics Division manufactures diagnostic products showed non-compliance with the GMP requirements. Areas of non-compliance included process validation, corrective and preventive action and production and process controls. The company's failure to comply with these requirements increases the likelihood that the diagnostic products produced at these facilities may not perform as intended.

Subsequent inspections, including one as recent as July 1999, showed little improvement in the company's compliance, despite three warning letters from FDA. Since 1995, FDA repeatedly encouraged the company to achieve compliance voluntarily. Despite assurances by the company that it would correct the manufacturing problems, the firm failed to bring its manufacturing operations into compliance. Ultimately, in order to protect the public health, FDA sought action by the Department of Justice.

Public health significance of non-compliance

It is important to understand the public health significance of FDA's Quality System regulation. When a manufacturer complies with the regulation, there is a level of assurance that the

product has been properly designed and manufactured in a consistent way and will perform as intended. Conversely, a manufacturer who fails to comply is less likely to produce a product that performs as intended. We are especially concerned about Abbott Diagnostic Division's long-standing non-compliance with these accepted manufacturing principles because they represent the minimum requirements for manufacturing quality.

What does the firm's failure to comply with the Quality System regulation mean for the users of its diagnostic products? It does not mean that these products will necessarily fail to perform as intended. It does mean that users have less assurance of successful performance than they would have had if these products had been manufactured properly.

The question of potential product shortages

FDA recognized that not having several of these products available could potentially cause shortages that could compromise patient care. To resolve this issue, the consent decree identifies those Abbott diagnostic products FDA currently believes to be medically necessary and for which there should be continued availability. A list of these devices is attached. Abbott Diagnostic Division will continue to distribute these medically necessary products while bringing the manufacturing of these devices into conformity with the Quality System regulation.

The remaining devices manufactured by Abbott Diagnostics Division, which are not included in the medically necessary provisions of the consent decree, will continue to be available for 30 days after the effective date of the consent decree, so that users can standardize or obtain alternative test methods.

Specific information on Abbott in vitro diagnostic products

Until the firm is in conformity with the Quality System regulation, FDA recommends that the Abbott diagnostic products which will remain available (per the attached list) be used in conjunction with quality control material made by other companies to increase the assurance of successful performance.

Updated information will be available on these products, as appropriate, via the internet at http://www.fda.gov/cdrh.

Information will also be available from the Center for Devices and Radiological Health (CDRH), Division of Small Manufacturers Assistance (DSMA) at 1-800-638-2041 and the CDRH Facts-on-Demand at 1-800-899-0381 document number 1127.

Specific information on Abbott blood screening products

On September 15, 1999, FDA informed Abbott that all of its viral marker test kits used to test blood and blood components are now subject to lot release by FDA's Center for Biologics Evaluation and Research (CBER). Due to this additional control measure, FDA believes that the test kits listed in the attachment can continue to be used without compromising patient care. FDA is not recommending that blood and blood components currently in distribution be retested. Updated information will be available on these products, as appropriate, via the internet at http://www.fda.gov/cber. Information will also be available from the CBER voice information system at 1-800-835-4709, the CBER FAX information system at 1-888-CBER-FAX, and to subscribers of CBER's automated mailing system, CBERINFO.

We will be contacting you again in the near future as more information becomes available.

Sincerely yours,

David Feigal, M.D., M.P.H.
Director, Center for Devices and Radiological Health

Kathryn C. Zoon, Ph.D.
Director, Center for Biologics Evaluation and Research

Attachment

LIST OF DEVICES WITH CONTINUED AVAILABILITY

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