

RESPONSE TO WARNING LETTER 2004-DT-01

February 18, 2004

Food and Drug Administration
Detroit District
Attention: Mr. David M. Kaszubski
Director Compliance Branch
U.S. Food & Drug Administration
300 River Place, Suite 5900
Detroit, Michigan 48207

Dear Mr. Kaszubski:

This letter is a direct RESPONSE to the WARNING LETTER 2004-DT-01, posted by the FDA on the official FDA website. We request that this official response letter be posted online directly under the FDA Warning Letter to inform the general public and all physicians that we have compliance with all FDA Mammography regulations.

The FDA has issued Basha Diagnostics, P.C. official U.S. Department of Health and Human Services Public Health Service Food and Drug Administration certificates, which do state that all Basha Diagnostics P.C. facilities are Certified Mammography Facilities.

These valid certificates state that all Basha Diagnostics, P.C. facilities are compliant with all requirements of the Mammography Quality Standards Act of 1992, and are hereby authorized to perform mammography examinations, pursuant to 42 U.S.C.263b.

All Basha Diagnostics P.C. Mammography facilities successfully meet all requirements of the FDA, ACR, State of Michigan and independent physicists for quality control and all rules and regulations for Mammography service.

Sincerely,

Y. Mossa Basha, M.D.,
President
BASHA DIAGNOSTICS, P.C.