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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

April 7, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Margie Villegas, Associate Director
Segundo Ruiz Belvis Diagnostic Treatment Center, Inc.
545 East 142nd Street
Bronx, New York 10454

REF: NYK-2000-61

Facility ID: 201533

Dear Ms. Villegas:

Your facility was inspected on March 21, 2000 by a representative of the New York City Bureau of Radiological Health, acting in behalf of the Food and Drug Administration. This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

The system to communicate results is not adequate because there is no system in place to provide timely lay summaries.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided at the close of the inspection. The Level 2 finding is:

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The processing speed (using the STEP procedure) is 74 for standard processing.

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

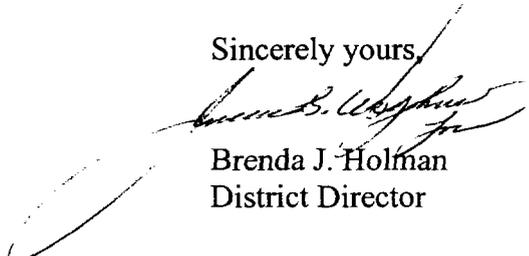
- The specific steps you have taken to correct the violations noted in this letter including supporting documentation; and
- Each step your facility is taking to prevent the recurrence of similar violations.

Please submit your response to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov/cdrh/dmgrp.html>.

If you have any questions about mammography facility requirements in general, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely yours,



Brenda J. Holman
District Director

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cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

cc: Dorothy Pender
New York City Bureau of Radiological Health
2 Lafayette Street
New York, NY 10007

cc: James Sheffield
New York City Bureau of Radiological Health
2 Lafayette Street
New York, NY 10007

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bcc: HFC-210
HFA-224 (CFN: 2436746)
HFC-230
HFC-240
HFI-35 (redacted)
HFZ-322
HFZ-240
HFR-NE19 (R. Bernacki)
HFR-NE1 (D. Kolaitis)
HFR-NE100 (B. Holman)
HFR-NE140
HFR-NE1500 (M. Kurzman)
EI Jacket (Segundo Ruiz Belvis Diagnostic Treatment Center, Inc. – CFN: 2436746)
Legal Jacket
W/L File

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