

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of

ECUMED HEALTH GROUP

FDA Docket: 2004H-0322

a corporation,

and

AMADOR REYES,
JUAN C. CARRAI,
RICHARD W. STONE, M.D., and
ERLINDA E. ENRIQUEZ, M.D.,

individuals.

DEFENDANTS' ECUMED HEALTH GROUP AND AMADOR REYES
REQUEST FOR PRODUCTION OF DOCUMENTS

Defendants, Ecumed Health Group and Amador Reyes ("Defendants"), by and through its undersigned counsel, hereby propounds Requests for Production of Documents upon the Center for Devices and Radiological Health, Food and Drug Administration, United States Department of Health and Human Services' (the "Complainant"), to be answered within thirty (30) days.

I. DEFINITIONS

1. "Complainant" shall mean the Center for Devices and Radiological Health, Food and Drug Administration, United States Department of Health and Human Services', and its respective representatives, agents, employees, attorneys and accountants.

2. "Ecumed" shall mean the Respondent, Ecumed Health Group, Inc.

2004H-0322

INT 1

3. "Carrai" shall mean Respondent, Juan C. Carrai.
4. "Reyes" shall mean Respondent, Amador Reyes.
5. "Dr. Stone" shall mean Respondent, Richard W. Stone, M.D.
6. "Dr. Enriquez" shall mean Respondent, Erlinda E. Enriquez, M.D.
7. "Respondents" shall mean Ecumed, Carrai, Reyes, Dr. Stone and Dr.

Enriquez, collectively.

8. "Complaint" shall mean the Complaint filed by the Complainant against Respondents on July 19, 2004.

9. "Answer" shall mean the Answer and Affirmative Defenses of Defendants, filed in this matter.

10. "MQSA" shall mean the Mammography Quality Standards Act of 1992, as set forth in the Complaint.

11. "ACR" shall mean the American College of Radiology.

12. "Certificate" shall mean the MQSA certificate, as required by 21 C.F.R. § 900.11 (a), (b) (1) (ii).

13. "Penalty" shall mean the civil money penalties assessed under 42 U.S.C. § 263b (h) (3) (A) and 42 U.S.C. § 263b (h) (3) (D).

14. "And" and "or" as used herein are terms of inclusion and not of exclusion, and shall be construed either disjunctively or conjunctively as necessary to bring within the scope of each request any document and/or electronic data that might otherwise be construed to be outside its scope.

15. "Relating to," "evidencing" or "reflecting" means to make a statement about, refer to, discuss, describe, evidence, reflect, show, support, contain, comprise, identify, or

in any way to pertain to, in whole or in part, or otherwise to be used, considered, or reviewed in any way in connection with, the specified subject. Documents and/or electronic data that "relate to" a subject also include those which were specifically rejected and those which were not relied or acted upon.

16. "Communication" means the oral and written utterance, notation or statement of any nature whatsoever, by and to whomever made, including, without limitation, agreements and other understanding between or among two or more people, consultations, conversations, correspondence, dialogues, discussion, interviews, meetings, telegrams and telephone calls. This definition includes all communications for which you claim a privilege.

17. "Describing" means any document and/or electronic data that, in whole or in part, describes, characterizes, delineates, explicates, deliberates, evaluates, appraises, assesses or provides a general explanation of the specified subject.

18. "Document" or "documents" as used herein shall mean the original and any copy, regardless of its origin and location, of all writings of any kind whatsoever including, but not limited to, all abstracts, accounting journals, accounting ledgers, advertisements, affidavits, agendas, agreements or proposed agreements, analyses, appointment books, appraisals, articles of incorporation, balance sheets, bank checks, bank deposit or withdrawal slips, bank credit or debit memoranda, bank statements, blueprints, books, books of account, budgets, bulletins, bylaws, canceled checks, charts, checks, codes, communications, communications with government bodies, computer data or printouts, conferences, contracts, correspondence, data processing cards, data sheets, desk calendars, details, diagrams, diaries, disks or data compilations from which information can

be obtained or translated, drafts, drawings, electromagnetic tapes, files, films, financial calculations, financial projections, financial statements, graphs, handwritten notes or comments however produced or reproduced, indexes, insertions, instructions, internal accounting records, interoffice communications, invoices, ledgers, letters, lists, logbooks, manuals, memoranda, microfilm, minutes of meetings, motion pictures, newspaper or magazine articles, networks, nonconforming copies which contain deletions, notations or records of meetings, notes, notices of wire transfer of funds, outlines, pamphlets, papers, passbooks, periodicals, photocopies, photographs, pictures, plans, preliminary drafts, press releases, proposals, publications, punch cards, raw and refined data, receipts, recommendations, records, records of conferences or conversations or meetings, records of payment, reports, resolutions, results of investigations, schedules, schematics, sepias, shipping papers, slides, specifications, speeches, statements of account, studies, summaries, surveys, tape recordings, tax returns, telegrams, telephone logs and records, telephone and other conversations or communications, teletypes, telexes, transcripts, transcripts of tape recordings, video tapes, voice records, vouchers, work papers, worksheets, written notations, and any and all other papers similar to any of the foregoing.

Any document containing thereon or attached thereto any alterations, comments, notes or other material not included in the copies or originals or referred to in the preceding definition shall be deemed a separate document within said definition. Any document shall include all exhibits, schedules or other writings affected by or referenced in any such document or other writings necessary to complete the information contained therein or make it not misleading.

19. "Person" means any natural person, corporation, partnership, company, sole proprietorship, association, institute, joint venture, firm, governmental body, or other legal entity, whether privately or publicly owned or controlled, for profit or not-for-profit, or partially or fully government owned or controlled.

20. "Any" means one or more.

21. "Year" means calendar year.

22. The singular form of a noun or pronoun shall be considered to include within its meaning the plural form of the noun or pronoun, and vice versa. The masculine form of a noun or pronoun shall be considered to include within its meaning the feminine form of the noun or pronoun, and vice versa.

23. Regardless of the tense employed, all verbs shall be read as applying to the past, present and future as is necessary to make any paragraph more, rather than less, inclusive.

II. INSTRUCTIONS

For purposes of responding to these requests, the following instructions shall apply:

1. In each of your responses to these requests, you are requested to provide not only such information as is in your possession, but also all information as is reasonably available, whether or not it is in your possession. In the event that you are able to provide only part of the information called for by any particular request, provide all of the information that you are able to provide and state the reason for your inability to state the remainder.

2. Every request herein shall be deemed a continuing Request for Production. You are to supplement your responses promptly if and when you obtain relevant information, in addition to or in any way inconsistent with your initial response to any such Request for Production.

3. If you object to, or otherwise decline to answer, any portion of any request, please provide all information called for in that portion of the request to which you do not object or to which you do not decline to answer. If you object to a request on the ground that it is too broad (*i.e.*, that it calls both for information which is relevant to the subject matter of the action and for information which is not relevant), please provide such information as you concede to be relevant. If you object to a request on the ground that it would constitute an undue burden to provide a response, please provide such requested information as can be supplied without undertaking such undue burden. For those portions of any request to which you object or otherwise decline to respond, state the reason for such objection or declination.

4. The relevant period of time for these Requests for Production is from January 1, 2002 to the present.

III. REQUESTS FOR PRODUCTION

1. All documents and/or electronic data reflecting any and all FDA applications submitted by Ecumed for the purpose of either applying for, renewing, or reinstating the MQSA certification.

2. All documents and/or electronic data reflecting any and all Certificates issued by the FDA, or on behalf of Complainant, to Ecumed.

3. All documents and/or electronic data reflecting any and all interim notices and/or provisional Certificates issued by the FDA, or on behalf of Complainant, to Ecumed including, but not limited to the provisional certificate issued on June 8, 2001 as alleged in ¶ 13 of the Complaint.

4. All documents and/or electronic data supporting your contention that the ACR issued testing materials to Ecumed on June 11, 2001.

5. All documents and/or electronic data supporting your contention that ACR sent a letter to Ecumed on July 31, 2001, stating that its testing was delinquent, as alleged in ¶ 15 of the Complaint.

6. All documents and/or electronic data reflecting or evidencing that any of the Defendants received notice of the July 31, 2001 letter from ACR.

7. All documents and/or electronic data supporting your contention that ACR notified any of the Defendants, specifically, that Ecumed's certificate would expire, as alleged in ¶ 16 of the Complaint.

8. All documents and/or electronic data supporting your contention that any of the Defendants, specifically, was advised by letter dated November 1, 2001, that Ecumed's MQSA Certificate would expire, as alleged in ¶ 18 of the Complaint.

9. All documents and/or electronic data supporting your contention that any of the Defendants, specifically, was advised that it/he could not lawfully conduct mammography examinations upon the expiration of the MQSA Certificate, as alleged in ¶ 19 of the Complaint.

10. All documents and/or electronic data supporting your contention that any of the Defendants were aware of, and understood, the administrative procedure required by the MQSA.

11. All documents and/or electronic data supporting your contention that any of the Defendants, specifically, was advised on December 21, 2001, that Ecumed's mammography unit failed to comply with the ACR's standards for clinical quality imaging, as alleged in ¶ 22 of the Complaint.

12. All documents and/or electronic data supporting your contention that Ecumed's mammography unit failed to comply with the ACR's standards for clinical quality imaging.

13. All documents and/or electronic data supporting your contention that Reyes was involved with Ecumed's application for reinstatement of October 14, 2002.

14. All documents and/or electronic data reflecting or evidencing that any of the Defendants received notice that Ecumed could not be provisionally reinstated, as alleged in ¶ 24 of the Complaint.

15. All documents and/or electronic data supporting your contention that ACR discussed with any of the Defendants the testing information that Ecumed need to submit, as alleged in ¶ 25 of the Complaint.

16. All documents and/or electronic data supporting your contention that any of the Defendants conducted mammography examinations between December 9, 2001 and May 5, 2003.

17. All documents and/or electronic data reflecting or evidencing that any of the Defendants knew that performance of mammography examinations after the alleged expiration date constituted a violation of the MQSA, as alleged in ¶ 30 of the Complaint.

18. All documents and/or electronic data supporting your contention that penalties in the sum of \$1,211,000.00 should be imposed against any of the Defendants.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was sent via facsimile and U.S. Mail on this 24th day of February, 2005 to:

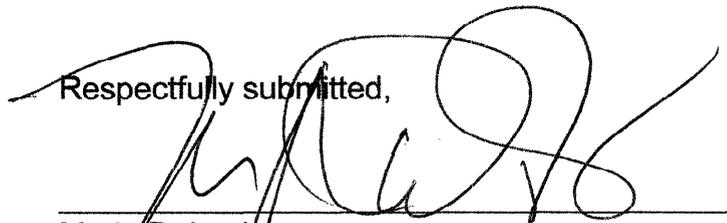
Michael N. Varrone
Attorney for Complainant
5600 Fishers Lane (GCF-1)
Rockville, MD 20857

Steven R. Ballinger
Attorney for Erlinda Enriquez
888 South Andrews Avenue, Ste. 205
Fort Lauderdale, FL 33316

Michael S. Kaufman
Attorney for Richard Stone
11900 Biscayne Blvd., Ste. 511
Miami, FL 33181

Juan C. Martinez
Attorney for Juan Carlos Carrai
FOWLER WHITE BURNETT P.A.
Espirito Santo Plaza
1395 Brickell Avenue, 14th Floor
Miami, Florida 33131-3302

Respectfully submitted,



Mario Delgado
Fla. Bar No. 745065
Mario R. Delgado, P.A.
2000 Ponce de Leon Blvd., Suite 102
Coral Gables, FL 33134
Telephone: (305) 774-9210
Facsimile: (305) 774-7310