

Professional Conduct Comprehensive Compliance

1. Purpose: To establish a program designed to materially comply with applicable federal and state laws and industry standards relating to the marketing and promotion of products. To insure that Top Management properly directs employees with regards to practices that support Comprehensive Compliance.
2. Scope: All employees will be governed by this procedure. Vendors and customers should be advised of this part of the QMS as needed.
3. Procedures:
 - 3.1. **Educational Grants and Research Grants**

Mayer Labs may provide grants for specific educational purposes that benefit consumers and customers. These may include, but are not limited to, continuing medical and paraprofessional education programs, fellowships provided to teaching institutions and similar organizations with a demonstrated commitment to public health, medical, scientific and technical education, and programs operated by organizations that provide high-quality, nationally recognized patient/consumer education. Funding of educational programs may generally be provided only to organizations and institutions and not to individuals. Research grants to support consumer-initiated research may be provided for programs involving research in areas of legitimate interest to the company. All requests for funding of research activities are subject to Top Management review prior to funding approval.
 - 3.2. **Charitable Contributions and Patient Assistance**

Mayer Labs may consider charitable contributions and requests for client assistance in the areas of family planning, sexual/reproductive health, healthcare education, access to healthcare and community responsibility, consistent with Mayer Labs' Vision and Mission.
 - 3.3. **Travel Expense Reimbursement for Continuing Medical Education (CME), Promotional, or Product Training Meetings**
 - 3.3.1. Mayer Labs will not, with very limited exceptions that are in accordance with nationally recognized standards, reimburse for travel and lodging expenses of attendees, other than Mayer Labs Employees, at promotional and educational programs.
 - 3.3.2. Mayer Labs Employees will not accept, with very limited exceptions that are in accordance with nationally and culturally recognized standards, reimbursement for travel and lodging expenses at

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Reference copy printout 8/18/05	Page 1 of 4	DN 3119-0 Effective Date: August 4, 2005

Professional Conduct Comprehensive Compliance

promotional and educational programs sponsored by vendors or consultants.

3.4. Business Meals

- 3.4.1. Mayer Labs occasionally may offer a modest meal as part of an educational presentation or a business discussion. The appropriate focus of these activities is an informational presentation or business discussion. Modesty is to be judged by local standards, but in general cost of meals with customers, employees, vendors, and officials should not exceed \$25 for breakfast, \$50 for lunch or \$125 for dinner.
- 3.4.2. Mayer Labs Employees may occasionally be offered a modest meal as part of an educational presentation or a business discussion. The appropriate focus of these activities is an informational presentation or business discussion. Modesty is to be judged by local standards, whether domestic or international, but in general cost of meals with vendors should not exceed \$25 for breakfast, \$50 for lunch or \$125 for dinner.

3.5. Provision of Educational and Practice-Related Items (Gifts)

- 3.5.1. On occasion, Mayer Labs representatives may provide patient or practice-related items to customers. These items must be of reasonable value (less than \$100) and infrequent. Promotional items of nominal value (less than \$25) such as coffee cups, pens, and notepads are permitted. These items usually feature a company or product logo.
- 3.5.2. On occasion, Mayer Labs Employees may be given a gift from a vendor. These items must be of reasonable value (less than \$100) and infrequent. Promotional items of nominal value (less than \$25) such as coffee cups, pens, and notepads are permitted. Any gift given to an Employee that exceeds the limits stated above should be reported to the Compliance Officer.

- 3.6. **Total Annual Dollar Limit for Meals and Educational or Practice-related Items** Mayer Labs has established an annual limit of \$2,500 for meals and educational or practice-related item(s) as the aggregate value of the items or activities that may be provided to any single healthcare professional business associate, customer or consultant, whether in the State of California or other jurisdiction, pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765).

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Reference copy printout 8/18/05	Page 2 of 4	DN 3119-0 Effective Date: August 4, 2005

Professional Conduct Comprehensive Compliance
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- 3.7. **Prohibition on Entertainment During Work Functions**
 - 3.7.1. In general, entertainment (e.g., sporting events, golf outings, concerts, sailing, vacations, etc.) is not permitted as part of Mayer Labs sales activities. In circumstances when customers are hosting events that are part of a recognized charity – fund raiser, part of the customer’s business development activities, or under the auspices of a recognized national trade association (e.g., NACDS, AmFAR, GMDC, ECRM, Planned Parenthood Federation, etc.) recreational or social events in conjunction may occur provided they are clearly subordinate in terms of time and emphasis between Mayer Labs and the Customer.
 - 3.7.2. In general, entertainment (e.g., sporting events, golf outings, concerts, sailing, vacations, etc.) is not permitted as part of Mayer Labs Employee activities, if not sponsored by Mayer Labs. In circumstances when vendors are hosting events that are part of a recognized charity – fund raiser, part of the vendors business networking - development activities, or under the auspices of a recognized national trade organization an Employee may attend provided his/her manager has approved of such attendance.

- 3.8. **Assigned Compliance Officer** Mayer Labs has appointed the Management Representative as the person responsible for the Company’s compliance with this Procedure. Our Compliance Officer has been empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to Top Management.

- 3.9. **Training** Mayer Labs will provide an annual Professional Conduct Comprehensive Compliance training for our Employees that covers applicable guidelines governing our compliance program. Employees are also trained on the consequences of failure to comply with the requirements of the Company’s Professional Conduct Comprehensive Compliance Program.

- 3.10. **Communication** Mayer Labs encourages open and candid discussion between management and Employees regarding compliance to this Procedure. Mayer Labs’ Employees are encouraged to report their concerns to their manager, to the Human Resources Department, or to the company’s Compliance Officer.

- 3.11. **Auditing and Monitoring** Mayer Labs self-assesses and periodically audits its compliance with its policies and procedures.

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Reference copy printout 8/18/05	Page 3 of 4	DN 3119-0 Effective Date: August 4, 2005

Professional Conduct Comprehensive Compliance
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- 3.11.1. Mayer Labs will annually declare, in writing, that it is in compliance with this Professional Conduct Comprehensive Compliance Procedure.
- 3.11.2. Mayer Labs will make its Professional Conduct Comprehensive Compliance Procedure, and its annual written declaration of compliance with the Program, available to the public as required by any relevant prevailing regulation and requirement.

3.12. **Enforcement and Disciplinary Guidelines** Mayer Laboratories will take disciplinary action in response to violation of the Company’s Professional Conduct Comprehensive Compliance Procedures. Disciplinary actions will be consistent with Mayer Laboratories, Inc. Employee Handbook.

3.13. **Responses to Detected Problems and Actions to Correct Issues** Mayer Labs requires a prompt and diligent response to potential violations of the company’s Professional Conduct Comprehensive Compliance Procedure, including its standards regulating the marketing and promotion of our products. Actions in response to detected problems may include improving policies, procedures, training, communication, monitoring, or may require disciplinary action to prevent future violations.

4. Safety Precautions: N/A

5. References:	<table style="border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;"><u>Document No.</u></th> <th style="text-align: left; border-bottom: 1px solid black;"><u>Topic</u></th> </tr> </thead> <tbody> <tr> <td>DN 4101</td> <td>Mission, Vision, & Quality Policy</td> </tr> <tr> <td>DN 4215</td> <td>Quality Systems Standards</td> </tr> <tr> <td colspan="2">Mayer Laboratories, Inc. Employee Handbook</td> </tr> </tbody> </table>	<u>Document No.</u>	<u>Topic</u>	DN 4101	Mission, Vision, & Quality Policy	DN 4215	Quality Systems Standards	Mayer Laboratories, Inc. Employee Handbook	
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Page 4 of 4		