

Community Integrity
Honesty
Respect Innovation

Our Company

Our Values

Our Future



Healthcare Compliance Policies

July 1, 2005

DECLARATION OF COMPLIANCE

As of July 1, 2005, DFB Pharmaceuticals, Inc. and the DFB Family of Companies believe to the best of their knowledge and information and based upon their good faith understanding of California law, that they comply in all material respects with DFB's comprehensive compliance program as set forth in the DFB Healthcare Compliance Policies and with California Health and Safety Code §§ 119400-119402.

DFB Pharmaceuticals, Inc. and the DFB Family of Companies are committed to conducting business in a lawful and ethical manner. Therefore DFB has adopted a comprehensive Healthcare Compliance Program reflecting our Core Values of **Honesty & Integrity, Customer Commitment,** and **Community.** The program is in accordance with the program described by the Department of Health and Human Services Office of Inspector General in its April 2003 “Compliance Program Guidance for Pharmaceutical Manufacturers” and reflects DFB’s adoption of the PhRMA “Code on Interactions with Healthcare Professionals.” It is the responsibility of each and every employee of a DFB Company to comply with these DFB Healthcare Compliance Policies.

1.0 COMPLIANCE WITH LAWS AND REGULATIONS

We shall comply and conduct our businesses in accordance with the highest ethical standards and in compliance with all applicable federal, state, national, and local laws and regulations. Honesty and Integrity shall at all times be our primary points of reference.

2.0 COMPLIANCE WITH LAWS AND REGULATIONS GOVERNING FRAUD & ABUSE

2.1 Anti-Kickback Statute

We shall not improperly offer or pay anything “of value” to either directly or indirectly influence someone to purchase, utilize, prescribe, or recommend any of our products or services. Our activities will be structured to fit within relevant “safe harbors” where applicable.

2.2 False Claims Act

We shall strive to ensure the accuracy of all data, statements, and claims made to government officials by us or by any other party at our direction or with our encouragement or assistance. We shall not operate in “deliberate ignorance” or “reckless disregard” of the truthfulness of such data, statements or claims.

3.0 COMPLIANCE WITH LAWS & REGULATIONS GOVERNING PROMOTION

3.1 Labeling

We shall submit all materials containing product messages to an internal multidisciplinary label committee for review and approval prior to our use of such materials.

3.2 Off-Label Promotion

We shall not request, recommend, encourage or promote an unapproved use of a product.

3.3 Marketing the Spread

We shall promote our products based on their safety, efficacy, cost, and other benefits, but not based on the amounts these products receive in reimbursement.

3.4 Switching

We shall promote our products based on their safety, efficacy, cost, and other benefits, not by offering or paying anything of value directly or indirectly to encourage or reward such a switch.

3.5 Lanham Act

We shall strive to ensure that all references to competitors are both true and accurate and are not used in a misleading fashion.

3.6 State Promotional Laws

We shall educate ourselves on state laws governing the promotion of prescription products and any reporting requirements therein and shall seek to comply with all such laws when applicable.

3.7 DFB's Annual Monetary Limit Per Clinician

Except in states whose laws require otherwise, we shall not provide meals or items whose aggregate value exceeds \$1000 to any single clinician in any single calendar year.

4.0 COMPLIANCE WITH LAWS & REGULATIONS GOVERNING PRIVACY

4.1 HIPAA

We shall not solicit, intentionally receive, or utilize identifiable health information. In the event we are inadvertently exposed to identifiable health information, we shall not record, utilize, or disclose such information except as required by law and / or judicial process.

4.2 State Laws

In addition to our policy concerning HIPAA, we shall seek to educate ourselves on relevant state privacy laws and to comply with any unique requirements of such laws.

5.0 COMPLIANCE WITH LAWS & REGULATIONS GOVERNING PRESCRIPTION PRODUCT SAMPLING & DISTRIBUTION

5.1 PDMA

We shall label, distribute, and account for all samples of our prescription products in accordance with the requirements of the Prescription Drug Marketing Act.

5.2 State Laws

We shall seek to inform ourselves about all state laws applicable to the sampling and distribution of our products and to comply with all such laws.

6.0 COMPLIANCE WITH THE PHARMA CODE

6.1 General Interactions

We shall ensure that our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions shall be focused on informing healthcare professionals about our product; providing scientific and educational information, and supporting medical research and education.

6.2 Meals

We shall only provide meals to healthcare professionals that are occasional, modest by local standards, occur in a venue conducive to educational discussions, and are accompanied by an informational presentation that provides scientific or educational value. We shall not include spouses or guests that do not qualify based on their status as a healthcare professional and shall not provide meals without a company representative present to conduct an informational presentation.

6.3 Entertainment

Outside of bona fide consulting relationships, we shall not offer or provide entertainment to healthcare professionals or those who can influence expenditures under federal or state healthcare programs.

6.4 Continuing Medical Education

We shall provide all financial support for continuing medical education and third party educational and scientific conferences directly to the CME or conference sponsor in compliance with the sponsor's guidelines, with no strings attached and no control over the speakers, faculty, content, educational methods, materials or venue of the educational activity. No subsidy for travel, lodging, or personal expenses will be provided to anyone other than a speaker and any meals provided will be subordinate to the educational activities and in accordance with the sponsor's guidelines.

6.5 Consultants

We shall only use healthcare professionals as consultants when such professionals are selected based on their expertise and ability to satisfy a legitimate need of our Company(ies) that we have identified in advance. All such bona fide consultants will be employed under a written agreement and paid a reasonable compensation that reflects the fair market value of their services determined in advance and shall only be reimbursed for travel, lodging and other expenses reasonably necessary and directly related to the consulting services being provided. The number of consultants used for any specific purpose shall be the minimum number necessary to satisfy the needs identified and services provided by consultants shall be in an appropriate venue. All requests for consulting agreements shall be submitted to and prepared by legal and the Company will retain records concerning the services provided.

6.6 Speakers Bureaus

We shall provide all healthcare professional participants in our Speaker's Bureaus with extensive training on Company products as well as on FDA requirements regarding communication about prescription products to ensure that such speakers provide a valuable service to the Company. A written consulting agreement for participants is required which shall provide for compensation at the reasonable fair market value for the speaker's services and reimbursement of necessary expenses for reasonable travel, lodging and meals which are directly related to the services being provided. All members of a Speaker's Bureau shall also meet all criteria for consultants.

6.7 Scholarships & Educational Funds

Any educational assistance for healthcare professionals to attend medical conferences shall only be provided to medical students, residents, fellows, and other healthcare professionals in training that have been selected by their academic or training institution to attend a major educational, scientific, or policy-making meeting of a national, regional, or specialty medical association.

6.8 Gifts

We shall not give healthcare professionals cash, cash equivalents, or gifts intended to personally benefit the healthcare professional. We shall only occasionally provide healthcare professionals with items that benefit patients (excluding product samples provided in accordance with the PDMA) that are valued at less than \$100 and are otherwise consistent with DFB's Annual Promotional Monetary Limit. We shall only provide healthcare professionals with practice-related items (pens, notepads, and similar "reminder" items with a Company or product logo) that are of minimal value.

6.9 Independence of Decision Making

We shall not provide or offer grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items to a healthcare professional in exchange for utilizing, recommending, or prescribing products or for a commitment to continue utilizing, recommending, or prescribing our products. We shall not offer or provide anything to a healthcare professional in a manner or on conditions that would interfere with the independence of such professional's independent clinical judgment or prescribing practices.

7.0 COMPLIANCE WITH LAWS & REGULATIONS GOVERNING PRICE REPORTING

7.1 Medicaid Rebate Statute

We shall ensure the accuracy of all "Best Price" and "Average Manufacturer Price" data (as defined by the Medicaid Rebate Statute) reported to government agencies by using accurate net pricing data that reflects all applicable discounts and price concessions to customers no matter how these discounts or concessions are described.

7.2 Public Health Service Act ("PHS")

We shall ensure the accuracy of the data we use to establish the prices charged to eligible entities under the PHS statute.

7.3 Veteran's Healthcare Act of 1992 ("VHA")

We shall ensure that all non-federal average sales price data reported to the federal government reflects all applicable discounts and price concessions offered for a product no matter how these discounts or concessions are described.

8.0 COMPLIANCE WITH VETERAN'S HEALTH ADMINISTRATION (VHA) DIRECTIVE 2330-060

8.1 Contacts with VA Staff

We shall ensure that our contacts with VA personnel are by appointment only, do not occur in restricted areas or with restricted personnel, and otherwise comply with applicable VHA directives.

8.2 Promotional Materials & Activities

We shall promote our products in VA facilities in accordance with both VA & FDA requirements & restrictions, shall indicate the appropriate formulary status of our products, shall seek any required prior approval for educational speakers, shall disclose our sponsorship of any educational program sponsored in a VA facility, and shall otherwise comply with applicable VHA directives.

8.3 Drug Samples & “Free Goods”

Any samples of our products distributed to VA facilities or clinicians shall be delivered to the Chief of Pharmacy Services, or one with similar responsibilities, to ensure proper storage, dispensing, and documentation for these samples. All products provided to VA clinicians for evaluation will be pre-approved by the Chief of Pharmacy Services and the local Pharmacy & Therapeutics Committee. No samples will be provided to VA clinicians for their personal or family use.

8.4 Gifts Including Refreshments

We shall only provide food items of nominal value to VA personnel when incident to a scheduled meeting or a legitimate educational interchange and otherwise consistent with an individual VA facility’s requirements. All other gifts or donations, including grants, educational materials, and textbooks, shall be provided directly to the VA medical facility.

9.0 COMPLIANCE WITH ETHICAL GUIDELINES CONCERNING GRANTS

9.1 Educational Grants

We shall only provide educational grants that have been pre-approved by an internal multidisciplinary grant committee and whose purpose is to provide scientific or educational advancement of the practice of medicine. Through our support via educational grants, we shall not reward, solicit, or encourage the utilization, prescription, recommendation, or purchase of our products and we shall not exercise any control over the content or conduct of the educational or scientific activity receiving our support.

9.2 Continuing Medical Education (CME) Grants

We shall only provide CME grants that comply with the accrediting body’s requirements and that do not reward, solicit, or encourage the utilization, prescription, recommendation, or purchase of our products.

10.0 COMPLIANCE WITH LAWS, REGULATIONS & GUIDELINES CONCERNING PHARMACOVIGILANCE

We shall comply with all laws and regulations concerning the reporting of potential problems regarding product safety, product quality, or product performance of any product that we market. We shall also work to establish effective internal pharmacovigilance practices for safety reporting of problems that we receive from all sources, including our field sales personnel, competitors, and consumers.

11.0 EXCLUDED OR INELIGIBLE PERSONS & PARTIES

We shall not employ individuals who have been convicted of a criminal offense related to a federal healthcare program or who are otherwise excluded, suspended, debarred or ineligible to participate in federal healthcare programs. We shall routinely compare our applicants, employees, consultants, and contractors, both current and potential, against the “List of Excluded Individuals / Entities” maintained by the Department of Health and Human Services’ Office of Inspector General.

DFB COMPLIANCE PROGRAM REQUIREMENTS

To ensure our compliance with these policies, we agree that it is the responsibility of each of us to comply, and ensure that our co-workers comply, with these policies. Consequently, each of us agrees

- 1. to seek guidance whenever we have any question or concern about any of our activities,*
- 2. to report to our Corporate Compliance Department any violation or perceived violation of these policies of which we become aware,*
- 3. to seek and participate in healthcare compliance training at least annually,*
- 4. to train all new employees on our policies concerning healthcare compliance,*
- 5. to routinely audit our compliance with these policies,*
- 6. to certify our understanding of, and compliance with, these policies within fifteen days after the beginning of each calendar year,*
- 7. to certify to the public that each of our companies is in compliance with these policies and all applicable laws on an annual basis, and*
- 8. to hold ourselves accountable for our compliance with these policies through our incentive compensation and our eligibility for advancement and continued employment.*

DFB CORE VALUES

We share different religious, social, and ethnic backgrounds. We also share certain standards of behavior that are fundamental to a healthy and productive society. We believe these standards of behavior are encompassed in five **CORE VALUES**:

Honesty and Integrity.

We conduct our business in compliance with all applicable laws and regulations. In addition, we are committed to uncompromising business ethics with honesty and integrity as our primary points of reference.

Customer Commitment.

We are committed to provide innovative, value-added products and services to our customers, the healthcare industry, and to the medical professionals, patients, and society in which we operate. We strive to communicate openly and honestly with our customers, to anticipate their needs and exceed their expectations.

Community.

We are responsible to the communities in which we live and work. We are committed to act responsibly in connection with our environment and natural resources.

Respect for our employees.

Our employees are our greatest assets. We recognize that our employees' hard work and their commitment to excellence determine our success. We value the health and safety of each individual in every location. We strive for diversity in our workforce and to honor our differences. We seek to provide all employees with opportunities for development and advancement. We require our management to be competent, just, and ethical.

Innovation.

The success of our Company depends on a cycle of continuous improvement and innovation. We set challenging goals for ourselves; we seek out new ideas and nurture their growth utilizing sound business and financial practices. We recognize that long-term growth and success require sound profits and reasonable reserves for adverse times.



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DFB Healthcare Compliance Policies

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