

Confidential: Proprietary Information
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Animal Health Policies and Procedures
February 1, 2013



**Clearly
Compliant**

Policies and Procedures



Bayer HealthCare

BHHC2013

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INTRODUCTION

This booklet, “**Bayer HealthCare Animal Health Compliance Policies and Procedures**,” contains vital rules and procedures that you are required to understand and follow. These policies and procedures are an essential part of the **HealthCare Compliance Program** for the Animal Health Division. The HealthCare Compliance Program includes, among other things, the Policies and Procedures in this booklet, the Bayer HealthCare Code of Conduct, and the HealthCare Compliance Training. The program provides employees, contractors, consultants and agents with the knowledge and training to act ethically and with proper judgment in various activities related to sales, and marketing, as well as interactions between Bayer employees, contractors, consultants and agents.

Animal Health Manual “Interactions with HealthCare Professionals”, BHC AG, may be found at http://us.bsp.cnb/apps/BSP/US/BSP-NJ/BSP-NJ.nsf/id/EN_Animal_Health

HealthCare Professionals include individuals or entities which are involved in the provision of healthcare services and/or items to patient and which purchase, lease, recommend, use arrange for the purchase or lease of or prescribe Bayer products in the U.S. It includes both veterinarians and their staff (e.g., registered veterinary technicians, and assistants) and others who do not provide services to patients but who are involved in the decision to purchase such as office staff, purchasing agents at hospitals, practice managers and management within group purchasing organizations (GPOs).

Note: All other Bayer customers or business guests, who are not “HealthCare Professionals”, including but not limited to employees of feedlots, stockers, integrators, other food animal entities, retailers, consultants, key opinion leaders (KOLs), advisory panels, or veterinary students are “Business Guests” and our interactions with these Business Guests, are governed by Bayer’s Corporate Compliance Policy, Bayer’s Gift Policy (for Customers, Vendors, Suppliers and any other entities or persons with whom Bayer does or intends to do business with) and Bayer’s T&E policy. In fact, under these policies, the same principles guide our interactions with HealthCare Professionals, guide our interactions with Business Guests and other entities and their personnel with whom Bayer does business and has business relationships. For example, meals, entertainment and gifts must be infrequent, reasonable in value, and reasonably related to our business concerns.

Importance of Complying with HealthCare Policies and Procedures

The laws governing our conduct are enforceable by criminal, civil and administrative penalties. Violations may result in jail sentences, fines, or exclusion from Federal and State programs. Bayer is committed to complying with all applicable laws and regulations and industry codes, governing the sale and marketing of animal health products. Failure to comply with Federal regulations and Bayer’s policies and procedures can have direct and severe consequences both to you and Bayer.

Any Bayer employee, contractor, consultant or agent who violates, or encourages others to violate, the Animal Health Compliance Policies and Procedures is subject to a broad range of discipline, up to and including termination of employment. Each Bayer HealthCare employee, contractor, consultant and agent will be required to include a compliance objective that is relevant and meaningful to his/her job responsibilities in his or her Performance Management Process. Performance on that compliance objective will be evaluated by each employee, contractor, consultant and agent's manager.

Employees, contractors, consultants and agents are required to report suspected violations of these Compliance Policies and Procedures to their supervisor, the Law and Patents Department, or the Bayer HealthCare Compliance Officer. Reports may also be made anonymously and confidentially via Bayer's Confidential Disclosure Program, which includes a toll free number (Bayer IntegrityLine), **1-888-765-3846**. Any employee, contractor, consultant or agent who in good faith reports a suspected violation, or raises any compliance matter, will not be subject to any retaliation or adverse action based upon such reports.

Bayer AG Global Corporate Compliance Policy

In addition to the **HealthCare Compliance Program** described above, the **Corporate Compliance Policy** published by Bayer AG in Germany covers the various Bayer sectors on a global basis. This Policy provides guidance regarding important areas of corporate responsibility, including the laws of various countries that impose obligations on Bayer and its employees, contractors, consultants and agents. The Corporate Compliance Policy may be found at: <http://www.bayer.co.th/webphp/eng/compliance.php>

Although the scope of the compliance programs differs, the concepts reflecting Bayer's commitment to ethical behavior are consistent, and Bayer employees, contractors, consultants and agents are required to comply with all Bayer Animal Health Compliance Policies and Procedures, including those specified in this booklet.

Bayer HealthCare AG Compliance Manual

The principles set forth in the Bayer HealthCare AG Compliance Manual also represent a broad outline of the minimum standards of business conduct that Bayer HealthCare AG expects each of its employees, globally, to follow. These minimum standards are derived from globally applicable laws, industry codes and internal regulations, and are consistent with the laws, regulations, guidelines and Compliance Policies and Procedures applicable in the US. However, where stricter local US standards exist, these always take precedence.

The Foreign Corrupt Practices Act

Animal Health conducts its business with the highest legal and ethical standards and will not tolerate corruption. Each employee, contractor, consultant and agent must perform his/her job in full compliance with the Foreign Corrupt Practices Act (FCPA) and must never conduct business through unlawful payments, bribes, kickbacks, gifts, or other questionable inducements.

The FCPA specifically prohibits Animal Health employees, contractors, consultants or its agents from offering, promising, making, authorizing, or providing directly or indirectly, any payments, gifts, or anything of value to a non-U.S. government official, political party or candidate, or an official of an international organization (such as the World Bank), with the intent to:

- Improperly influence or reward the official's actions;
- Improperly influence decision-making in order to obtain or retain business; or
- Secure an improper advantage.

Each Bayer Animal Health employee, contractor, consultant or agent has the responsibility to ensure that his/her dealings with non-U.S. government officials—including state-employed healthcare professionals—comply with the FCPA. Likewise, each employee, contractor, consultant and agent is prohibited from making payments to any third party who the employee, contractor, consultant or agent knows will, or believes is likely to, make an unlawful payment related to Bayer Animal Health's business.

Questions

It is expected that every employee, contractor, consultant or agent will have a working knowledge of the laws affecting his/her responsibilities and the scope of permissible activities involved in his/her work, and will seek guidance from a supervisor, the Law and Patents Department or the Bayer HealthCare Compliance Department concerning any matter on which there is a question.

1. BUSINESS MEALS AND ENTERTAINMENT WITH HEALTHCARE PROFESSIONALS

Under certain circumstances, Bayer Animal Health representatives may provide an occasional modest business meal to a veterinarian and their staff in an appropriate setting in connection with a discussion or educational presentation involving Bayer Animal Health products, disease states, and related issues. Entertainment must be secondary to the main purpose at the event (education, discussion of Bayer Animal Health products and disease states) and is not allowed as a stand-alone. In addition, spouses or other guests are not allowed. Bayer Animal Health policies prohibit employees, contractors, consultants and agents from offering anything of value, including business meals, to a veterinarian to encourage the veterinarian to prescribe, purchase, or order Bayer Animal Health product(s), or to recommend the prescription, purchase, or ordering of Bayer Animal Health product(s). Offering or providing items of value, including business meals, to encourage veterinarians to prescribe, order, or recommend Bayer Animal Health products could violate state consumer protection statutes. As a general rule, no business meals should be offered to veterinarians (or their staff) who are not current customers.

SCOPE

The policy covers interactions with all veterinarians and their staff.

Bayer Corporation has additional corporate policies regarding business meals and other business interactions that fall outside this policy and do not cover healthcare professionals specifically. You may find these policies at: <http://www.bayernet.com/corp/policies/>

GENERAL RULE

Meals may be provided to healthcare professionals if they are: (1) occasional (2) modest; (3) incidental to a *bona fide* presentation or discussion of Bayer Animal Health products, disease states relevant to Bayer Animal Health products, medical education, or other legitimate business discussions related to Bayer Animal Health products; (4) take place in a setting conducive to such discussion; and (5) involve only individuals who are necessary for the conduct of Bayer Animal Health business.

SETTING FOR BUSINESS MEALS

Business meals and entertainment should be provided with an educational component consisting of a discussion of Bayer Animal Health products, a discussion of disease states relevant to Bayer Animal Health products, medical education, informational presentations, or other legitimate business discussions related to our products or business and the educational component should be more than 50% of the event. Taking a veterinarian to dinner or any other meal solely to discuss personal issues (e.g., mere “relationship building”) is not acceptable. The meal and appropriate discussion must occur in a place

and manner conducive to business discussion. Accordingly, offering meals without a company representative present or providing “take-out” meals are not allowed.

SPENDING LIMITS AND FREQUENCY

Spending for meals and entertainment should not exceed \$125 (or as judged by local standards) per attendee. The limit includes food, beverages, tax and tip. When you provide an informational presentation, such as an educational or product presentation to a veterinarian, you may include a modest meal. However, the definition of “modest” will often depend on circumstances surrounding the event. For example, for conferences and speaker events, a “modest” meal would be what a veterinarian would routinely spend on dining at his or her own expense. For more informal occasions, such as office visits or business, meals should generally be limited to snacks or sandwiches. Such meals may only be provided on an occasional basis, which generally shall mean no more than **five** times during the calendar year.

It is important to remember that the government may view business meals that are provided too frequently or are too expensive as an improper inducement to purchase Bayer Animal Health products.

Some states (e.g., Minnesota, where Bayer Animal Health does not allow any spend on practitioners or staff) have separate – and very strict – laws regarding the provision of business meals and other promotional activities that are more restrictive than Bayer Animal Health’s general policy. Please refer to the Policy and Procedure 4, “State Laws”, in this booklet for details of these restrictions. If you interact with veterinarians from any of these states, you must consult the relevant Bayer Animal Health procedures **prior** to providing any item of value to those veterinarians.

EXAMPLES

The following are examples of appropriate business meals:

- Taking a veterinarian to a modest lunch to discuss BAYTRIL®
- Bringing in pizza to a veterinarian’s office for a “lunch and learn” on PROFENDER®

The following are examples of meals that are **NOT appropriate**:

- Giving your credit card to a veterinarian and telling him/her to “buy lunch” or make some other purchase (credit card provided in this manner is a “cash equivalent”; no Bayer Animal Health employee present; no educational presentation)
- Taking a veterinarian to lunch, who has never purchased Bayer Animal Health Product (appears to be an inducement to prescribe)
- Taking a veterinarian and spouse to dinner or in a “foursome” with your spouse (including a spouse or guest at a business meal is always inappropriate)
- Taking a veterinarian to a renowned or extravagant venue or locations predominantly known for their leisure, wellness, relaxation or entertainment value (Animal Health Manual “Interactions with HealthCare Professionals”, Spring 2009, BHC AG 3.5.3)
- Taking a veterinarian to a self-standing sightseeing tour or high profile, inappropriate or expensive entertainment (Animal Health Manual “Interactions with HealthCare Professionals”, Spring 2009, BHC AG 3.5.3)

MEALS AT SPEAKER PROGRAMS, SPEAKER TRAINING, CONSULTANT ADVISORY BOARD MEETINGS

Modest meals or receptions are permitted during company held educational meetings where an informational presentation, speaker training or consultant/advisory boards in conjunction with an informational presentation is provided. A “modest” business meal in this context should cost no more than \$125 per person (or as judged by local standards). For example, selecting a high end restaurant noted for lobster tails and filet mignon would not be a modest meal. Such meals shall be provided in a venue conducive to the educational purpose of the event. Alcoholic beverages must be kept at a minimum. It is prohibited to pay for the cost of a spouse for a healthcare professional.

Some states (e.g., Minnesota, where Bayer Animal Health does not allow any spend on practitioners or staff) have separate – and very strict – laws regarding the provision of business meals, educational items and other promotional activities that are more restrictive than Bayer Animal Health’s policies. Please refer to the Policy and Procedure 4, “State Laws”, in this booklet. If you interact with veterinarians from any of these states, you must consult the relevant Bayer procedures prior to providing any item of value to those veterinarians.

PROCEDURES

Before providing a business meal, ask yourself:

1. Will the frequency and the total value for all educational items and business meals to this veterinarian and/or organization be considered modest and reasonable?
2. Will there be a product or scientific discussion?
3. Is the venue appropriate?
4. Is the amount modest?
5. Am I reasonably certain that there are no additional considerations, such as whether the veterinarian is a government employee or practices in a state with special restrictions or reporting requirements?

The answers to all five questions should be “yes” for the business meal to be appropriate.

Documentation of Business Meals and Entertainment

Business meals and entertainment with veterinarians and business guests are recorded through your Travel and Entertainment Expense Report (“T&E”) under Professional Education Meal. All employees must document the details of business expenses according to IRS rules, Compliance Policies and Procedures and the Corporate T&E Policy. An accurate description (e.g., describes what product you are detailing as well as purpose for the detailing visit to the veterinarian’s office) of the business purpose must be documented. Instructions on how to complete your T&E when providing a business meal to a veterinarian or business guest can be found on the intranet at: <http://www.compliance.bayerweb.com/Video20100817/player.html>

Itemized (detailed) receipts and copies of the Attendee Sign in Sheet must be included with every professional education meal expense entered into Concur T&E regardless of the amount. **These two requirements supersede the Corporate T&E Policy.**

The failure to submit for reimbursement for the business meal and entertainment does not circumvent the business meal policy.

All business meals where veterinarians and other office staff are in attendance, whether in or out of the office, regardless of amount require an itemized (detailed) receipt and a completed sign in sheet which documents the attendance of each individual. If the Bayer

Animal Health employee pays for the meal on his/her credit card and will expense the meal through the Concur system, the sign in sheet must be attached to the T&E report. Meals paid on behalf of Bayer Animal Health through a third party vendor also require sign in sheets. Sign in sheets used at third party meals (such as speaker programs or Ad Boards) must be submitted in accordance with

The sign in sheet must have the following information:

General

- Event date
- Event location (in-office or out of office)
- Event type (education session, dinner speaker program, advisory board, speaker training, etc.)
- Program/Event number (if applicable)
- Event host (Bayer employee)
- Signatures of all Bayer HealthCare employees
- Speaker (if applicable) printed and signature
- Contract number (if applicable)
- Name and address of Venue
- Number of licensed veterinarians, non-licensed veterinarian's office staff, Bayer Employees, Total attendees

Per Individual veterinarian and staff

- Contract number (if applicable)
- Printed name
- Title (credentials)
- Affiliated entity or company

- Full address (address, city, state, zip)
- HCP license number (if applicable) <http://hcp.sln.bayernet.com/Login.aspx?ReturnUrl=%2fDefault.aspx>
- State of license (if applicable)
- Signature. Bayer Animal Health employees may, if necessary, complete information other than the signature. **Each HCP must sign for himself/herself.** If you are unable to obtain a signature, you must contact the Bayer HealthCare Compliance Department or the Law and Patents Department prior to submitting your expense report.

Supervisor Review of T&Es

Complying with expense reporting and approval policies is a critical responsibility for managerial employees to ensure proper control of legitimate expenses incurred during business meals provided for business purposes.

Immediate supervisors are responsible for regularly reviewing T&E for all employees they oversee to ensure that they are consistent with this Policy and Procedure and other applicable Bayer Animal Health requirements, including that the limit per person per meal is not exceeded, that the attendees are appropriate, that the venue is appropriate, and that the total number and amount of business meals provided to any single healthcare professional are consistent with this Policy and Procedure.

If the review reveals potential divergence from Bayer Animal Health policy, the supervisor should take appropriate action to include discussing the situation with the employee, documenting corrective action and notifying the next supervisory level and the Law Patents Department. Please refer to Policy and Procedure 20, "Disciplinary Action."

RECORD RETENTION

T&E reports are retained by the Accounting Department for a period of time as required by law or the Corporate Record Retention Policy.

AUDITS

Spending for business meals is subject to audit by Corporate Audit and Bayer HealthCare Compliance to ensure compliance with this Policy, including proper documentation, spending limits, and company spending policy. The government (e.g., IRS) may also request to audit/review expense reports.

2. EDUCATIONAL ITEMS FOR HEALTHCARE PROFESSIONALS

Bayer Animal Health representatives may provide modest items, not of substantial value (less than \$100 retail) that are designed primarily for the education of patients or healthcare professionals no more than **twice** per year. Some states (e.g., Minnesota, where Bayer does not allow any spend on practitioners or staff) have separate and more restrictive spending limits and marketing codes. Please refer to the Policies and Procedures 4, “State Laws”, in this booklet for details. Bayer Animal Health policy prohibits employees, contractors, consultants and agents from offering anything of value, including an educational item, to a veterinarian (or staff) to encourage the veterinarian to prescribe, purchase, or order Bayer Animal Health product(s), or to recommend the prescription, purchase, or ordering of Bayer Animal Health product(s). Offering or providing educational items of value to encourage veterinarians to prescribe, order, or recommend Bayer Animal Health products could violate state consumer protection statutes. Educational items of modest value may be provided if the item primarily benefits animals, animal health, and/or relate to the veterinarian’s work. As a general rule, no educational items should be offered to veterinarians who are not current customers.

SCOPE

The policy covers interactions with all veterinarians and their staff.

MEDICAL TEXTBOOKS

This policy permits providing a textbook costing no more than \$100 in circumstances where the textbook will educate several veterinarians and their clients. As a general rule, no textbooks should be offered to veterinarians who are not current customers. Textbooks should be approved by Veterinary and Marketing Services. For the purposes of “occasional” shall mean no more than three times per calendar year.

You must always consider the retail value of a textbook along with other educational items and meals in determining if the items provided to any one veterinarian and/or practice could create the appearance of an improper inducement. Also, this policy should not be interpreted as permission to “build a personal library” for any veterinarian or veterinarian practice group.

Regardless of the amount spent, you are responsible for ensuring that the items provided to any one veterinarian and/or practice do not create the appearance of an improper inducement.

Other Printed Booklets and Text Materials

Other printed medical booklets and text materials such as review guides, pocket books, and handbooks, etc. may be obtained from Marketing by following the same procedures as for logo items. The purchase of any medical books or text materials without approval is prohibited.

Questions and Title Suggestions

All questions regarding availability and title suggestions for textbooks and other printed booklets should be communicated to the Director of your functional area who will then contact the appropriate Product Director in the Marketing Department.

Prior Review and Approval of all Printed Materials

Adherence to formal textbook initiative programs and following proper procedures for other booklets and printed materials ensure that the text in the materials you distribute is properly reviewed and approved for promotional distribution. Distribution of any printed material, textbook, or any other publication without proper technical review and approval is a direct violation of Bayer HealthCare's Code of Conduct and Compliance Policies and Procedures. Please refer to Policy and Procedure 15, "Materials for External Use," in this booklet for further details.

ACCEPTABLE EDUCATIONAL ITEMS

You may provide educational items, to a veterinarian or staff, which is designed for the education of animal owners or the healthcare professional. Examples of appropriate items include medical textbooks, anatomical models, animal self-assessment and tracking tools, written informational materials and animal starter kits.

It is Bayer Animal Health's policy to not provide subscriptions to scientific journals to a healthcare professional. Items of minimal value, practice related items such as pens, note pads, mugs "reminder" with the company or product logos, are permissible items. Educational items may never include payments in cash or cash equivalents, such as (a) gift certificates; (b) loans; (c) savings bonds; (d) lottery tickets; or (e) airline upgrade coupons; or (f) items for personal use.

The following are examples of appropriate educational items:

- Textbooks with prior approval by Veterinary and Marketing Services.

The following are examples of items that are NOT appropriate:

- Office or medical supplies (e.g., anything which could be considered expense relief).
- Any item, regardless of cost, that rewards a veterinarian for prescribing or purchasing Bayer Animal Health products.
- Gift cards including restaurants, food items, movie theaters, games, etc.
- Standalone tickets to entertainment, sports and other events.
- Items for personal use, not related to education or practice of medicine.

SPENDING LIMITS FOR EDUCATIONAL ITEMS

The limit for appropriate educational items is \$100 (retail value) per item. Such educational items may only be provided on an “occasional” basis which generally shall mean no more than **five** times during the calendar year. You are also responsible for using good judgment to ensure the aggregate value and quantity of educational items and/or business meals to any recipient is reasonable. Educational items and/or meals that are provided too frequently or are too expensive may be viewed as improper inducement to purchase Bayer Animal Health products.

Some states have separate – and very strict – laws regarding the provision of educational items and other promotional activities that are more restrictive than Bayer Animal Health’s policies. Please refer to the Policy and Procedure 4, “State Laws”, in this booklet. If you interact with veterinarians from any of these states, you must consult the relevant Bayer Animal Health procedures prior to providing any item of value to those veterinarians.

PROCEDURES

Before providing an educational item, ask yourself:

- Is it medically related, designed to primarily educate the animal owner or veterinarian and staff?
- Is the amount modest?
- Will the frequency and the aggregate value for all educational items and business meals to this veterinarian and/or organization be considered modest and reasonable?

- Am I reasonably certain that the recipient does not require additional considerations, such as whether he/she is a government employee or veterinarian who practices in a state with special restrictions or reporting requirements?

The answers to all four questions should be “yes” for the educational item to be appropriate.

Documentation of Educational Items through the T&E

Educational items except medical textbooks are recorded on your Travel and Entertainment Expense Report (“T&E”). Instructions on how to complete your T&E when providing an educational item to a veterinarian or business guest can be found on the intranet at:

<http://www.compliance.bayerweb.com/Video20100817/player.html>.

The failure to submit for reimbursement for the business meal and entertainment does not circumvent the business meal policy.

Supervisor Review of T&Es

Complying with the expense reporting and approval policies is a critical responsibility for managerial employees within the company, ensuring that control of proper expenses is executed for expenses that employees incur while conducting business.

Immediate supervisors are responsible for reviewing T&Es for all employees they oversee to ensure consistency with this Policy and Procedure and other applicable Bayer Animal Health requirements, the \$100 limit per educational item is not exceeded and that the total number and amount of educational items provided to any single practitioner are consistent with this Policy and Procedure, as well as reviewing for compliance with any other related Bayer Animal Health policy. Departments should have established procedures for prior approval of educational items to ensure compliance with this Policy and Procedures.

If the review reveals potential divergence from Bayer Animal Health policy, the supervisor should take appropriate action, to include discussing the situation with the employee, documenting corrective action, and notifying the next supervisory level and the Law Patents Department. Please refer to Policy and Procedure 20, “Disciplinary Action.”

RECORD RETENTION

T&E reports and invoices are retained by the Accounting Department for a period of time as required by law or the Corporate Record Retention Policy.

AUDITS

Spending for educational items is subject to audit by Corporate Audit and Bayer HealthCare Compliance to ensure compliance with this Policy, including proper documentation, spending limits, and company spending policy. The government (e.g., IRS) may also request to audit/review related spending.

3. PROVIDING SAMPLES AT NO CHARGE

Bayer Animal Health may provide a limited number of product samples of Bayer Animal Health products to customers at no charge. Samples are limited to initial customer product evaluation, education, training and/or for distribution directly to animal. The quantities of product samples provided must not exceed an amount that is reasonably necessary for the intended use of the samples. Providing product samples in violation of this policy is strictly prohibited.

The provision of product samples to customers must be documented in the Siebel system. Such documentation must contain, at a minimum, the number of samples provided to each veterinarian, lot numbers, the date the samples were provided and the licensed veterinarian's signature confirming the samples were received. Bayer Animal Health must conduct annual physical inventories of all product samples in control of each representative and maintain records of such inventory. Therefore, it is important that the provision of samples be recorded accurately.

Under no circumstances is a sample to be given to a veterinarian for personal use or for use by their immediate families or office staff – so-called "professional courtesy units." Offering free samples to healthcare professionals for their personal use potentially implicates the Anti-Kickback Statute if one purpose of the offer is to induce the professional to order or prescribe Bayer Animal Health products.

Product samples are not the same as charitable product donations. Samples are provided for animal or provider evaluation purposes only.

4. STATE LAWS

Connecticut – Compliance Program

COMPLIANCE PROGRAM

Connecticut requires pharmaceutical and medical device manufacturers (which includes prescription drugs and devices intended for animals) to adopt and implement a compliance program that is consistent with and contains, at a minimum, all of the requirements prescribed in the AdvaMed Code or PhRMA Codes, as such codes were in effect on January 1, 2010. Additionally, manufacturers must adopt a comprehensive compliance program in accordance with the "Compliance Program Guidance for Pharmaceutical Manufacturers," developed by the Department of Health and Human Services Office of Inspector General (OIG).

Manufacturers also are required to conduct training and regular audits of their compliance program.

As of October 5, 2012, no regulations have been implemented by the Connecticut Department of Consumer Protection, the agency tasked with enforcing the Connecticut compliance program law.

4. STATE LAWS

Louisiana – Restrictions on Interactions with State Executive Branch Officials (Including HealthCare Professionals)

Louisiana law prohibits public employees from accepting most gifts and other items of value. It also requires individuals who spend \$500 or more entertaining Louisiana executive branch officials to register as lobbyists and to report certain lobbying expenditures.

IDENTIFICATION OF LOUISIANA EXECUTIVE BRANCH OFFICIALS

A list of executive branch departments and agencies can be found on the State of Louisiana website at: <http://www.govengine.com/stategov/louisiana.html>. The list is not all-inclusive, and it is your responsibility to use due diligence in determining whether your interaction is with a member of a governmental body. If in doubt, ask the healthcare professional whether he/she is an executive branch official before providing any meal, gift, speaker fee, or other fee-for-service payment.

PROHIBITION ON GIFTS TO PUBLIC EMPLOYEES

Under Louisiana's gift law, the only items of value that state employees are permitted to accept are "promotional items" of a nominal value and "food and drink" consumed in the presence of the gift giver. **State employees may not accept medically-related gifts, speaker fees, textbooks, etc.** You should assume that healthcare professionals working at state facilities, such as state hospitals, universities, clinics and prisons are state employees. Under Louisiana law, they remain state employees even when they are not physically located at a state facility (e.g., on their days off or when working at a civilian facility). It is your responsibility to determine whether a Louisiana healthcare professional is a state employee before offering or providing a gift, meal, speaker fee, or other fee-for-service payment.

LOBBYING REGISTRATION AND DISCLOSURE

The Louisiana Lobbying Disclosure Act requires those who entertain or present before executive branch officials with the intent to influence executive branch action to register as lobbyists.

Because of the stringent reporting requirements as well as additional legal ramifications, no Bayer sales force employee should be registered as a lobbyist in Louisiana. (Note that Public Policy and Government Affairs employees must register as lobbyists as a requirement of their job.)

Under no circumstances should a Bayer Animal Health employee entertain or appear before an executive branch official without first contacting the Public Policy and Government Affairs Department well in advance of the contemplated activity.

FEE-FOR-SERVICE EVENTS

Louisiana's Code of Governmental Ethics prohibits a public servant from receiving compensation for services rendered by the public servant if such services are compensated by an entity from which the public servant may not receive a gift under Louisiana law. Accordingly, you must consult the Law and Patents Department before entering Bayer Animal Health into a financial arrangement with, reimbursing travel expenses for, and/or engaging any Louisiana healthcare professional as a consultant, advisor or speaker.

Louisiana law, however, provides a limited exception for faculty or staff members of a public higher education institution to provide certain consulting services in their field of expertise, provided the consulting arrangement is properly approved according to the process specified by Louisiana law. These Louisiana laws significantly impact the consulting arrangements that companies may enter into with healthcare professionals who are executive branch officials.

The Louisiana Board of Ethics has discussed the application of the gift law to pharmaceutical fee-for-service arrangements with Medicaid P&T Committee members and in a number of Advisory Opinions. Some of the key Advisory Opinions regarding fee-for-service arrangements with employees of Louisiana public universities are discussed below.

Louisiana Public University Employees

Ethics Advisory Opinion No. 2006-247 (April 18, 2006) and 2006-654 (September 14, 2006) analyzed fee-for-service arrangements between pharmaceutical companies and employees of Louisiana public universities. Although no Advisory Opinions appear specifically to address this issue in the context of veterinary medicine, the prohibitions apply to public university employees, which could include practitioners of veterinary medicine. The Board concluded as follows:

- Although Louisiana law does provide a limited exception for faculty or staff members of a public higher education institution to provide certain consulting services in their field of expertise (provided the consulting arrangement is properly approved according to the process specified by Louisiana law), speaking engagements are not considered consulting services. Therefore, executive branch officials who are employees of public universities in Louisiana may **not** accept compensation or related travel reimbursement for serving as a speaker at a seminar or other speaking engagement. There is an exception for certain consulting services (discussed below), but payment of travel expenses and/or a speaker fee in connection with an executive branch official's participation as a speaker at a seminar or other speaking engagement does not meet this exception.

- Furthermore, the exception that permits executive branch officials to provide consulting services under certain conditions (discussed below) does not apply to speaking engagements.
- Under certain conditions, executive branch officials employed by Louisiana public universities may serve as paid consultants to a company to serve on an advisory board to assist in product development or to provide advice on other issues particular to the practice of medicine including developing continuing medical education materials. However, the following conditions must be met first:
 - The services must be related to the executive branch official's academic discipline or area of expertise, and
 - Proper approval must be granted in writing by the chief administrative officer of the State agency in compliance with Section 1123(9)(b) of the Code of Governmental Ethics.
- Executive branch officials may be reimbursed for travel expenses related to a study or clinical research trial only if the contract between Bayer and the State agency obligates Bayer Animal Health to pay for all reasonable travel expenses incurred by participating veterinarians in connection with trial related meetings.

In summary, the Louisiana gift law places significant restrictions on the fee-for-service arrangements that Bayer Animal Health may enter into with Louisiana executive branch officials. The Louisiana statutory provisions are very complex, and are often amended by the legislature or subject to new interpretations by the Louisiana Board of Ethics. Again, you must consult the Law and Patents Department before entering Bayer Animal Health into a financial arrangement with, reimbursing travel expenses for, and /or engaging any Louisiana health care professional as a consultant, advisor or speaker.

4. STATE LAWS

Minnesota – Promotional Spending Limits and Cost Reporting

You must not provide any educational items, meals, or other items of value to any practitioner licensed in the State of Minnesota or anyone employed by them.

It is the policy of Bayer Animal Health to follow state laws regarding gifts and business meals even when such laws are more restrictive than Bayer's standard policy. The State of Minnesota limits gifts and business meals provided to any licensed practicing veterinarian to an aggregate total of \$50 per year from all Bayer Divisions. To ensure that Bayer does not exceed the \$50 annual limit, no Bayer employee may provide educational items or meals to any practitioner, including veterinarians and their staffs, licensed to practice in Minnesota.

SCOPE

For purposes of the Minnesota law, "practitioner" includes any licensed practicing Minnesota veterinarian (D.V.M.) and staff.

This policy applies to all practitioners licensed in the State of Minnesota, regardless of where the transaction occurs.

EXCEPTIONS TO ANNUAL SPENDING LIMIT

The following expenditures do not count toward the \$50 annual spending limit:

- Professional samples of a drug provided to a prescriber for free distribution to animals.
- Payments to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner, practice, or professional corporation and the payment is used solely for *bona fide* educational purposes (pursuant to a valid sponsorship agreement).
- Reasonable speaker fee and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting (pursuant to a valid fee-for-service agreement).
- Compensation for professional or consulting services of a practitioner in connection with a genuine research project (pursuant to a fee-for-service agreement).
- Product or company publications and educational materials.
- Salaries or other benefits paid to Bayer employees who are Minnesota practitioners.

- Meals and other approved expenses provided in connection with speaker training meetings and advisory boards/consultants meetings (where these practitioners are engaged by Bayer Animal Health under contract to perform services). Payments for these services must be reported to the State, as described below.
- Funds provided by Bayer Animal Health to a non-Bayer sponsor of an industry meeting or convention. Non-Bayer sponsor means the event is a third party event, with no Bayer Animal Health involvement in the creation, development or organization of the event (e.g., selection of speakers, topics, etc.) and pursuant to a valid Sponsorship Agreement. For example, Bayer Animal Health may provide funds to a sponsor of an educational program, provided that the sponsor is not a professional corporation owned by practitioners or a distributor or agent of Bayer Animal Health. Bayer Animal Health hospitality suites at industry meetings must always be funded through the meeting sponsor and must be open to all meeting attendees.
- Product publications and other product educational materials.

APPLYING THE LIMITS

To ensure that Bayer does not exceed the \$50 annual limit, **you must not provide any gifts or meals or other items of value to any practitioner licensed in the State of Minnesota or anyone employed by them.** This includes any licensed Minnesota practitioners who may be practicing in other states. This policy applies to any licensed Minnesota practitioner and their staff, regardless of where they practice. This limit is cumulative and applies to all Bayer Divisions (Dermatology, Pharmaceutical and Animal Health businesses combined), not individual Bayer employees.

Note: Meals and other approved expenses provided in connection with speaker-training meetings and advisory boards/consultant meetings do not count toward the annual \$50 limit. However, payments to practitioners for these services must be reported to the State as described below.

- Textbooks are included in the \$50 limit on gifts to Minnesota practitioners. Thus, textbooks cannot be provided to individual veterinarians (see Policy and Procedure 2, "Educational Items for HealthCare Professionals").
- Marketing surveys are included in the \$50 limit. Although the limit does not apply to fee-for-service arrangements, as described below, payments for "marketing

surveys” are interpreted by the Minnesota Board of Pharmacy as “gifts” and therefore are subject to the limit.

- The \$50 spending limit does not apply to Bayer funds provided to a non-Bayer sponsor of an industry meeting or conference. Bayer Animal Health may also provide funds in excess of \$50 to the sponsor of an educational program, provided that the sponsor is not a professional corporation owned by practitioners. Bayer Animal Health hospitality suites at industry meetings must be funded through the meeting sponsor and be open to all meeting attendees.
- Bayer Animal Health product samples, product publications and other product educational materials are also excluded from the \$50 spending limit.

COST REPORTING

Effective January 1, 2012, the Physician Payment Sunshine Act (PPSA), also known as Patient Protection and Affordable Care Act (PPACA) has preempted any state law that requires a manufacturer to disclose the type of information covered by the federal report. Since the vast majority of the data that is reported under the Minnesota law is information covered by the federal report, the Minnesota Board of Pharmacy has determined that for calendar year 2012 it will not require Manufacturers to report any data. However, the Bayer policy prohibiting meals and gifts in Minnesota remains in effect since the gift ban portion of the law has not been preempted.

Bayer Animal Health employees must internally report all payments, regardless of dollar amount, to Minnesota practitioners (as defined above) via the appropriate reporting method (e.g., Concur).

The internal reporting requirement applies to all payments made to practitioners licensed in Minnesota, regardless of where the services were rendered. Payments to be reported include, but are not limited to:

- Speaker fees;
- Consultant fees;
- Advisory board fees;
- Data purchases;
- Market research data; and
- Expense reimbursements.

Note that payments for “marketing surveys” are interpreted by the Minnesota Board of Pharmacy as “gifts”. Therefore, Bayer should not use Minnesota-licensed practitioners for marketing surveys for which compensation is paid by Bayer or a third party vendor administering the survey. Under the Bayer HealthCare Code of Conduct, payments for grants, research projects (clinical trials), and payments to sponsors of medical education programs must be made to an organization rather than to an individual practitioner or a practice group. Payments to entities unrelated to practitioners generally do not need to be reported under the Minnesota statute.

BAYER-SPONSORED MEETINGS PLANNED THROUGH THIRD PARTY VENDORS OR THE BAYER MEETING PLANNERS

Bayer Animal Health representatives responsible for planning a Bayer-sponsored meeting or program must work with the third party vendors responsible for such meetings to ensure the vendors report the required data to the Bayer Animal Health representative in order to meet the State reporting laws. If data cannot be collected and reported, then the Bayer Animal Health representative is responsible for excluding from the invitee list all reportable healthcare practitioners licensed in Minnesota, and any other state with similar reporting requirements or spending limits. Also, Bayer Animal Health representatives contracting with a third party vendor for meeting planning services must also ensure the contract clearly states either: 1) that within one month (30 days) from the date of payment to practitioners, the vendor will provide the required data (providing a description) to the Bayer Animal Health representative in order to satisfy the specific reporting requirements; or 2) that the vendor will exclude healthcare practitioners from Minnesota and any other state with similar reporting requirements or payment limits.

4. STATE LAWS

Nevada – Marketing Code of Conduct

Nevada law requires each manufacturer that employs a person to sell or market a drug (prescription or non-prescription) or prescription device in Nevada to “adopt a written code of conduct which establishes the practices and standards that govern the marketing and sale of its products.” The definitions of “manufacturer” and “drug” under Nevada law encompass manufacturers of drugs intended for animals. The code of conduct must be based on applicable legal standards and “incorporate principles of health care.” The statute specifies that principles of healthcare include requirements that the company’s sales and marketing activities are “intended to benefit patients, enhance the practice of medicine, and not interfere with the independent judgment of healthcare professionals.” A marketing code of conduct that incorporates the most recent version of the Code on Interactions with HealthCare Professionals issued by the Pharmaceutical Research and Manufacturers of America (the “PhRMA Code”) will be deemed to satisfy this element of the Nevada statute. In addition, the statute requires that manufacturers identify a compliance officer who will be responsible for “developing, operating, and monitoring” the code of conduct.

Further, Nevada law requires manufacturers to adopt a training program to “regularly” educate all “appropriate” employees, including all sales and marketing personnel on the marketing code of conduct. In addition, the statute mandates annual audits to monitor the Company’s compliance with its marketing code of conduct.

Manufacturers are required to adopt policies and procedures for investigating noncompliance with the code of conduct. The policies and procedures must establish a reporting structure within the company that will promote effective lines of communication. In addition, the policies and procedures must describe how the company will investigate reports of noncompliance reports and what corrective actions the company will take in response to noncompliance. Finally, the policies and procedures must require the company to report instances of noncompliance to law enforcement authorities “in appropriate circumstances.”

Manufacturers must annually file with the Nevada Board of Pharmacy the following information:

- A copy of the company’s marketing code of conduct;
- A description of the company’s training program;
- A description of the investigation policies;
- The Compliance Officer’s name, title, address, telephone number, and e-mail address; and

- A certification that the company has conducted its annual audit and is in compliance with the marketing code of conduct.

Every other year, the Board will submit to the Governor and the legislature a report that compiles the information from the annual submissions. The Board will also publish on the Internet information concerning company compliance with the statute. The statute prohibits the Nevada Board from disclosing any proprietary or confidential information.

Implementing regulations contain a compliance form that must be completed annually and submitted to the Nevada Board of Pharmacy by June 1 of each year.

4. STATE LAWS

Tennessee – Ethics Commission Act

Tennessee law does not require vendors or their representatives in Tennessee to register as lobbyists; representatives must, however, comply with provisions similar to those of a lobbyist.

The law states that vendors shall not offer or attempt to offer anything of value to an official in the legislative or executive branch, to any candidate for state office, or to immediate family members of such officials or candidates. This prohibition includes meals, travel expenses, and lodging. Product samples and product informational materials are not a part of the gift ban and can be given to anyone if otherwise permissible under applicable laws and Bayer Animal Health Compliance Policies and Procedures. Promotional items (e.g., pens, clocks, pads of paper, etc.) that might otherwise be permitted under Tennessee law are prohibited under Bayer Animal Health Compliance Policy and Procedure 2, “Educational Items for Healthcare Professionals.”

A Sales Representative cannot buy a meal for any member of the Tennessee legislative or executive branch. This includes state representatives and senators, TennCare officials, Department of Health officials, and anyone directly employed by the state of Tennessee. Also, Sales Representatives may not purchase any meals for veterinarians appointed to state boards like DUR or PAC committees.

Bayer Animal Health employees can buy a meal for county health department officials, First Health employees, and any hospital employed physician unless they are on a board stated above, to the extent the provision of the meal is consistent with Bayer Animal Health Compliance Policy and Procedure 1, “Business Meals and Entertainment with HealthCare Professionals.” (Note: Tennessee does not have any state owned hospitals.)

The Tennessee law applies only to state employees. Local ordinances could prohibit gifts otherwise permitted by Bayer Animal Health in a Tennessee county or city. Bayer Animal Health employees need to check with local governments for those regulations.

5. RESTRICTIONS ON INTERACTIONS WITH CERTAIN STATE EXECUTIVE AND LEGISLATIVE OFFICIALS AND STATE EMPLOYEES (INCLUDING HEALTHCARE PROFESSIONALS)

Most states and many municipalities regulate the activities of persons doing business with state officials or state employees through state lobbying and/or ethics reform statutes. Some states and municipalities require vendors and/or their representatives to register as lobbyists. Some states prohibit the receipt of state or municipal contracts if certain campaign contributions have been made to state or local candidates. Some states prohibit vendors from offering anything of value to certain state executive or legislative officials or state employees, and virtually all states prohibit the offering of anything of value to any official in return for an official act.

The categories of state officials or employees which may trigger state lobbying, pay to play, procurement, ethics statutes, or similar laws include:

- State employees, including employees of state hospitals;
- Clinicians with privileges at state-owned hospitals, even if not employed by the state-owned hospital;
- State hospital formulary committee members;
- State Medicaid P&T Committee members;
- State executive branch members and their immediate family members;
- Members of the state legislature and their immediate family members; and
- Other public officials, potentially including local officials.

The lobbying and ethics laws are often complex and vary from state to state. Therefore, sales representatives **must, in advance of detailing, providing business gifts or meals to, or otherwise interacting with** any of the above categories of individuals, contact the Vice President of Public Policy and Government Affairs to determine whether the contemplated activity triggers any lobbying, procurement or ethics laws in the state in which the activity will occur. If the activity potentially implicates a state lobbying, procurement or ethics law, the sales representative must receive written approval from the Vice President of Public Policy and Government Affairs Department before proceeding with the activity.

If the contemplated activity involves a Louisiana individual who falls into one of the above-referenced categories, please review the Policy and Procedure 4, "State Laws Louisiana – Restrictions on interactions with State Executive Branch Officials (Including HealthCare Professionals)."

6. CORPORATE MEMBERSHIPS

Bayer Animal Health participates in corporate memberships with various medical and patient organizations, as well as legislative policy groups and community organizations, in order to foster increased understanding of scientific, clinical, or healthcare issues that contribute to the improvement of animal care and/or support animal advocacy groups.

SCOPE

Animal Health organizations, as well as legislative policy groups, may require payment of a fee as a condition of membership. To the extent Bayer Animal Health wishes to become a member of such an organization, it is the policy of Bayer Animal Health to establish these memberships for the Corporation or Division and not for individual Bayer Animal Health employees.

Legislative policy groups offer Bayer Animal Health relevant industry information, provide Bayer Animal Health visibility within the industry, and promote goodwill within organizations that maintain a political voice. Membership in medical and other animal health organizations allows Bayer Animal Health to support the organization's educational and advocacy programs as well as participate in the membership benefits. Membership benefits vary depending on the organization and may include allowing Bayer Animal Health to attend educational meetings and to interact with fellow attendees such as healthcare professionals and/or clients.

Where applicable, Bayer Animal Health may promote products through a display or exhibit outside the main meeting or event room. Please refer to the Policy and Procedure 8, "Product Exhibits and Displays," for information on how to request and conduct such activities.

This policy does not cover individual Bayer Animal Health employees' memberships in professional organizations for the individual's professional growth and awareness of industry issues, such as the American Veterinary Medical Association, National Association of Pharmaceutical Sales Representatives, Medical Marketing Association, etc. Upon approval of your supervisor, individual professional organization memberships must be submitted through Concur T&E.

This policy does not cover educational grants or charitable contributions Bayer Animal Health may provide to an animal advocacy group or animal health organization. Such payments must comply with Policies and Procedures 9, "Education Grants (Including Continuing Education)" and 12, "Charitable Contributions (Other than Free Bayer Products)," respectively. Payment for a corporate membership is not a charitable contribution.

REQUIREMENTS

An organization may solicit membership through a web-site, e-mail, or paper mailing, or Bayer Animal Health may seek out an organization and request to become a member. The organization's main focus should be to increase understanding of scientific, clinical, or healthcare issues that contribute to the improvement of animal care or to support animal health advocacy. Membership at all levels offered to Bayer Animal Health must be open to other animal health companies.

Membership fees cannot be paid to entities that may purchase, prescribe, or recommend Bayer Animal Health products, such as private practice groups or hospitals. Likewise, no one at Bayer Animal Health should agree to pay membership fees to any organization or base the level of membership selected (e.g., platinum, gold, silver) if the membership or level is contingent on the purchase of Bayer Animal Health products or used as a price term.

It is Bayer Animal Health's policy to pay fair market value for corporate membership. Thus, Bayer Animal Health should pay the same fee as other corporate members for the same level or type of membership. The organization has sole control over the membership fees paid by Bayer Animal Health.

The membership must be for a Bayer Division or the Corporation, not an individual employee. Individual Bayer Animal Health employees may attend the organization's events to gain knowledge of the subject topic, interact with fellow attendees, demonstrate Bayer Animal Health's general support for the patient group and/or the organization's mission, etc.

Any promotional activities by Bayer Animal Health employees that may be permitted by the organization must occur outside the main meeting or event room. All materials used must be approved by the Legal, Medical, Regulatory Review Committee (LMR) and comply with Policy and Procedure 15, "Materials for External Use." Exhibits and display payments and activities must conform to the Policy and Procedure 8, "Product Exhibits and Displays."

PROCEDURES

Requestor

The Bayer Animal Health "Requestor" must be entitled to complete the "Bayer Certification for Corporate Membership Form." Administrative Assistants and other employees in clerical support positions cannot legitimately certify the points listed on the certification form and must not sign as the Requestor.

The Requestor must:

- Complete the "Bayer Certification for Corporate Membership" form.
- Generate an internal spending request by completing an "Internal Payment Demand/Check Request."
- Include any supporting documentation.
- Forward the completed payment request package to the Supervisor.

Supervisor

The Supervisor reviews all documentation and makes an independent judgment as to whether the Corporate Membership is consistent with Bayer Animal Health's policies. If appropriate, the Supervisor approves by signing the "Bayer Certification for Corporate Membership" and "Internal Payment Demand/Check Request" and forwards both documents to the Public Policy and Government Affairs Department.

If the Supervisor does not approve the request, he/she informs the Requestor that the proposed request has been denied.

Public Policy and Government Affairs Department

The Public Policy and Government Affairs Department reviews all documentation and makes an independent judgment as to whether the Corporate Membership is consistent with Bayer Animal Health's policies. It also confirms that the membership request does not duplicate an existing membership with the same organization. If appropriate, the Public Policy and Government Affairs Department approves by signing the "Bayer Certification for Corporate Membership" form and "Internal Payment Demand/Check Request" and forwards both documents to the Law and Patents Department.

If the Public Policy and Government Affairs Department does not approve the request, it informs the Requestor that the proposed request has been denied.

Law and Patents Department

The Law and Patents Department reviews all documentation and makes an independent judgment as to whether the contribution is consistent with Bayer Animal Health's policies. If appropriate, the Law and Patents Department approves by signing the "Bayer Certification for Corporate Membership" form and "Internal Payment Demand/Check Request" and forwards both documents to the Accounting Department.

If the Law and Patents Department does not approve the request, it informs the Requestor that the proposed request has been denied.

RECORD RETENTION

The Accounting Department must maintain the payment request package for a period as required by law or the Corporate Record Retention Policy.

AUDITS

All Corporate Membership payments are subject to audit by Corporate Audit to ensure compliance with these policies. The government (e.g., IRS) may also request to audit/review corporate memberships.

FORM: BAYER CERTIFICATION FOR CORPORATE MEMBERSHIP FEES

Name of Organization: _____

Amount of Membership Fee: \$ _____

Indicate by checkmark whether the following apply:

- ☐ The organization's primary mission is to increase understanding of scientific, clinical, healthcare or community issues that contribute to the improvement of animal care or animal health advocacy.
- ☐ Membership in this organization is for Bayer Animal Health and not an individual employee.
- ☐ The membership fee is not being paid to a customer or other entity that can purchase, prescribe, or recommend Bayer Animal Health products.
- ☐ The organization offers the same membership or membership level to other corporations for the same fee.
- ☐ The organization, not Bayer Animal Health, controls the disbursement of the membership fees.
- ☐ The membership fees are not charitable contributions or educational grants.
- ☐ The membership fee is not contingent on the price or purchase of Bayer Animal Health products.
- ☐ The membership fee is not contingent on lobbying activities on behalf of Bayer Animal Health.
- ☐ To the best of my knowledge, the information contained in this certification form is true.

Requestor Certification

Printed name: _____ Date: _____

Signature: _____

Supervisor Certification and Approval

Printed name: _____ Date: _____

Signature: _____

Public Policy and Government Affairs Certification and Approval

Printed name: _____ Date: _____

Signature: _____

Law and Patents Certification and Approval

Printed name: _____ Date: _____

Signature: _____

RECORD RETENTION INSTRUCTIONS

The Accounting Department must maintain the payment request package for a period as required by law or the Corporate Record Retention Policy.

7. SPECIAL REQUIREMENTS FOR FEDERAL GOVERNMENT EMPLOYEES

The federal laws and regulations governing items of value, including meals and educational items provided to federal government employees, including part-time federal government employees, are much stricter than the laws and regulations for non-government healthcare professionals. This policy and procedure will help you avoid any conduct that presents the appearance of impropriety when conducting business with employees of the federal government.

Who Qualifies as a Government Employee

A government employee includes anyone (military or civilian) employed by a facility associated with the Department of Defense (e.g., military or “DoD”), the Department of Veterans Affairs (“VA”), Federal Public Health Service (“PHS”), the Indian Health Service, National Institute of Health (“NIH”), or other federal government entities. According to federal law, a government employee includes part-time employees of the government and part-time workers at a government facility.

For example, the following are considered government employees:

- A resident while he or she is doing a rotation at the VA.
- A physician who works part-time at the VA and part-time at a civilian institution (the amount of time spent at the VA hospital is irrelevant).

Note: You may not exceed the dollar limits or other restrictions in this policy by providing educational items or business meals to a government employee at the civilian location.

GENERAL LIMITS

You may not offer or provide anything of value – regardless of the amount – to a federal government employee in order to influence him or her to prescribe, purchase, order, use or recommend any Bayer Animal Health product(s). You may also not provide any item of value to a government employee to encourage that employee to take, or not take, any action in his or her official capacity. Before providing any item of value to a healthcare professional, it is your responsibility to determine whether he or she is a federal government employee.

PROHIBITION OF EDUCATIONAL ITEMS AND BUSINESS MEALS

Federal law prohibits contractors such as Bayer Animal Health from providing educational items or business meals to federal government employees that exceed \$20 per government employee per event or a total of \$50 per government employee in a calendar year. This federal regulation is often referred to as the “20/50 Rule”. These limits apply to the entire Bayer HealthCare, not to an individual sales representative.

In order to ensure that Bayer complies with these limits, it is Bayer Animal Health policy that **Bayer Animal Health employees, contractors, consultants and agents may not provide educational items or business meals to federal government employees, regardless of dollar value.** Thus, educational items and meals to federal government employees are prohibited by this policy. **Business meals may be provided to a federal government employee if there is a fee for service arrangement (consultant or speaker) with this employee.**

Product samples and products provided for evaluation are not considered “educational items” and may be provided to federal employees, if permitted by the government entity and in accordance with applicable Compliance Policies and Procedures. You must check with the relevant authority at the government entity regarding their position on samples and product provided for evaluation before providing such products.

LIMITED EXCEPTIONS

Widely Attended Gatherings

Government officials are permitted by federal law to attend certain group events of a medical or educational nature, referred to as “widely attended gatherings,” sponsored by contractors such as Bayer Animal Health, even if the cost of these events exceeds the 20/50 Rule. Widely attended gatherings include events sponsored by industry associations that are open to both government and civilian officials (e.g., AVMA conference, NAVC). In order for the Bayer Animal Health sponsored event to be considered a “widely attended gathering,” the sponsored event must be open to all attendees of the conference or convention, (e.g., a Bayer Animal Health sponsored keynote address at the annual AVMA convention). Note that the sponsored event/meal itself, not just the conference, must be open to all attendees. Thus, you may not invite government employees to attend a Bayer Animal Health sponsored limited target audience event (e.g., dinner at a “Bayer table” at AVMA) or invite individual government officials to dinner at an AVMA conference or similar event.

Fee-for-Service Arrangements

Modest business meals may be provided to a federal government employee if there is a fee-for-service arrangement (consultant or speaker) with the federal employee and the meal is provided in connection with the fee-for-service arrangement (e.g., meal at an investigator meeting, meal at a speaker event). Because this exception is limited, you must consult your supervisor or the Law and Patents department before providing a meal to any federal employee.

8. PRODUCT EXHIBITS AND DISPLAYS

Exhibits and displays of Bayer Animal Health products are **promotional forums**, and must be compliant with prohibitions on off-label promotion under the Federal Food Drug & Cosmetic Act, or contain content compliant with the Federal Insecticide, Fungicide and Rodenticide Act or the FTC Act. All discussions with healthcare professionals must be consistent with product labeling. Sales and Marketing personnel may not discuss an unapproved drug, an unregistered product or an unapproved indication for an approved or registered product. These policies and procedures are designed to allow you to conduct exhibits and displays while abiding by the legal restrictions.

SCOPE

The purpose and business need for a product exhibit or display is for a third party event sponsor to provide the means and opportunity for Bayer Animal Health to display products, provide product information, and interact with veterinarians or other customers attending the event. Exhibit materials must be approved by the Marketing Material Review Committee (MMRC) and comply with Bayer Animal Health Compliance Policy and Procedure 15, "Materials for External Use."

This procedure covers both commercial exhibit booths, such as those set up at major conferences or conventions. A "commercial exhibit booth" usually includes exhibit property, graphics, and informational brochures and is used at national and regional medical conventions. The exhibit property and graphics are maintained and shipped from a third party exhibit house vendor. A "display" is held under the auspices of an association or similar organization and used to display approved Bayer Animal Health product information for program attendees.

RELATIONSHIP TO EDUCATION GRANTS

You should not use education grants to pay for exhibits or displays and it is not appropriate to receive **exhibit or display space** in return for Bayer Animal Health's payments for research or education grants or any charitable contribution. There may be situations where you wish to provide an education grant to an organization (e.g., for a veterinary conference) and also display or exhibit at that same conference. Ideally, these activities should be processed as separate transactions by submitting a request for an education grant as well as complying with these procedures to cover the display or exhibit fee. However, circumstances may be such that there is no meaningful separation of exhibit fee in the documentation submitted by the requesting organization. It is common for an organization to extend an invitation for exhibit space at an associated event in their written request document for an education grant or charitable contribution. In these situations, it may be necessary to submit only one payment request with the total dollar amount covering both the exhibit space and the grant

funds or charitable contribution amount. The approval process for the grant or charitable contribution procedure needs to be followed in these situations. For more information on Education Grants, see Policy and Procedure 9, "Education Grants (Including Continuing Education)," in this booklet.

APPROPRIATE PROMOTIONAL ACTIVITIES

Commercial exhibits and displays are **promotional forums**. All discussions with veterinarians must be consistent with product labeling (e.g., they must be on-label). Sales and Marketing personnel shall not discuss an unapproved Bayer Animal Health product or unapproved indication for an approved Bayer Animal Health product. Only promotional materials approved for distribution may be located in and distributed from a commercial exhibit or display. Bayer Animal Health personnel should not initiate any off-label discussions with any customer. Further, if foreign Bayer Animal Health products are exhibited or displayed at veterinary conferences, these displays must be separated and visually clear that these products are not for sale within the United States.

9. EDUCATION GRANTS (INCLUDING CONTINUING EDUCATION)

This Policy describes the appropriate use of grants to fund medical education activities that foster increased understanding of scientific, clinical, or health care issues that contribute to the improvement of animal care. Bayer Animal Health's policy conforms to FDA's Draft Policy statement on Industry-Supported Scientific and Educational Activities (EPA) and appropriate guidelines pursuant to RACE or other accredited CE certification.

The Policy prohibits offering an education grant to a veterinarian to encourage the veterinarian to prescribe, purchase, or order Bayer Animal Health product(s), or to recommend the prescription, purchase, or ordering of Bayer Animal Health product(s). Offering an education grant to encourage veterinarians to prescribe, order, or recommend Bayer Animal Health products could constitute a violation of state consumer protection statutes.

DEFINITION OF EDUCATION GRANT

Bayer Animal Health may provide funding for educational activities associated with educational conferences, continuing education (CE) programs or professional meetings if they are sponsored by an organization other than Bayer Animal Health and they will contribute to the improvement of patient care. Education grants may only be made to organizations, such as a conference sponsor, to foster increased understanding of scientific, clinical, or health care issues that contribute to the improvement of animal care. Education grants may not be provided to individuals or private practice groups. This policy also applies to grants to any governmental agency. The organization may use the grant funds for overall program expenses or specifically for speaker(s), meal(s), reception, etc. Grant funds cannot be used to offset indirect or other expenses not directly related to the educational program nor can they be used for travel expenses of the attendees. A grant should never be made if one purpose of the grant is to provide a financial inducement for dispensing or ordering Bayer Animal Health products or to encourage off-label use, or to reward referrals for Bayer Animal Health products.

Bayer Animal Health may provide financial assistance for educational activities associated with **educational conferences, continuing education (CE) programs or professional meetings** if they are sponsored by an organization other than Bayer Animal Health and they will contribute to the improvement of animal care. The Bayer Animal Health employee is responsible for confirming if necessary, that the recipient organization's own policies allow it to receive the proposed grant.

Once grant funds are provided to the grant recipient, no one at Bayer Animal Health may control or influence the purposes for which the grant is utilized.

Bayer Animal Health may offer financial assistance to permit **veterinary students** to attend major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations only if the selection of individuals is made by the academic or training institution.

Promotional Speaker events controlled by Bayer Animal Health are not considered “educational grants” for purposes of these policies. Policy and Procedure 10, “Fee-for-Service Arrangements,” in this booklet applies to these events.

It is important to determine whether a request for support is a charitable contribution, corporate sponsorship or education grants. The terminology used by the entity requesting the funding (e.g., “charitable contribution,” “grant”) is not the determining factor because organizations may submit funding requests using inconsistent or incorrect terminology. The key factors are the type of entity requesting the funding (e.g., non-profit, patient organization, hospital) and focus of the event or activity (e.g., education, fundraising). For example:

- A **charitable contribution** is funding provided to a non-profit organization to support the organization’s activities where Bayer Animal Health does not expect to receive anything in return and where the primary purpose of the event/activity is fundraising/charity rather than education.
- A **sponsorship** is funding provided to support the activities of a professional, medical or patient association or organization where Bayer Animal Health receives something of value, such as banners or signage at a conference or an opportunity to advertise in the association’s publication.
- An **education grant** is funding provided to support an event where the primary focus is educating the participants/attendees, rather than fundraising.

Key Characteristics: Charitable Contributions vs. Corporate Sponsorships vs. Education Grant

Characteristics	Charitable Contributions	Corporate Sponsorships	Education Grants
Promotional in nature	No	Yes	No
Payee must be a 501(c)(3) or other tax exempt organization	Yes	No	No
Bayer HealthCare receives something of value in return	No	Yes	No
Payment can be made to an individual HCP or private practice group	No	No	No
Tickets or invitations received as a result can be offered to veterinarians or other customers	No	No	No
Sales and Marketing Involvement	No	Yes	No

CONTINUING EDUCATION PROGRAMS

The CE programs must be for scientific or educational purposes and not for the purpose of promoting any product. Any discussion of Bayer Animal Health's products must be objective, balanced and scientifically rigorous. The vendor must submit a proposal to Bayer Animal Health describing the specifics of each educational program, including, but not limited to the date, time, location, scope, and budget. However, the vendor exercises full control over the planning of the program's contents, including the selection of attendees, presenters and moderators.

PROCEDURES

Before entering into an arrangement to sponsor CE programs with a vendor, the Bayer Animal Health employee must contact the Law and Patents Department to initiate the request. The Law and Patents Department maintains and controls the procedure applicable to the selection and contracting arrangements for these CE programs.

CE CONTRACTUAL PROVISIONS REGARDING VENDOR DISCLOSURES TO PROGRAM PARTICIPANTS

The contract between Bayer Animal Health and the vendor must require that the vendor disclose the following information to all program participants:

- Bayer Animal Health's funding of the program and any significant relationships between the vendor and Bayer Animal Health;
- Financial or other relationships between individual presenters or moderators and Bayer Animal Health;
- Any limitations on information that is presented at the programs such as data that represent ongoing research, interim analysis, preliminary data or unsupported opinion;
- When a Bayer Animal Health product or a competitor's product is to be the subject of substantial discussion, the data must be objectively selected and presented. Both favorable and unfavorable information about the product must be fairly represented and any discussion of the prevailing body of scientific information on the product and of reasonable, alternative treatment options must be balanced; and
- If applicable, the fact that uses of Bayer Animal Health product(s) that were discussed are not approved by the FDA.

BAYER ANIMAL HEALTH INVOLVEMENT IN EDUCATION GRANTS

The following applies to any educational program – including, but not limited to CE activities – **which includes or is reasonably expected to include information on unapproved uses of Bayer Animal Health products**, regardless of whether or not the event is sponsored in whole or in part by Bayer Animal Health.

1. Bayer Animal Health Attendance

- Sales and Marketing personnel may not attend such programs unless the request has been reviewed and approved in writing in advance of the program by their manager after consultation with the Law and Patents Department. Written approval may be made via electronic mail. Separate approval must be obtained for each event.

- Bayer Animal Health representatives attending such programs may not ask or “plant” questions in the audience that are likely to lead to off-label discussion.

2. Bayer Animal Health Independence

Bayer Animal Health employees may **NOT** be involved in the following activities associated with educational grants:

- Selecting the audience for any program funded by an educational grant.
 - Selecting the content, faculty, educational methods, materials or venue for any program funded by an educational grant. Bayer Animal Health may respond to **unsolicited written requests** from program providers for suggestions of names or sources of names for **possible speakers only**. Bayer Animal Health must provide (where reasonable) the names of more than one speaker, a description of each suggested presenter’s qualifications, and a disclosure of any significant financial or other relationship between Bayer Animal Health and the suggested presenter.
- ### 3. Promoting Bayer Animal Health or Bayer Animal Health products
- Bayer Animal Health employees who are given permission to attend an educational program supported by Bayer Animal Health grant funds may not engage in formal or informal promotional activities inside or outside the meeting room(s).
 - Bayer Animal Health employees who are not attending the program may conduct appropriate promotional activities outside program meeting rooms, such as at an adjacent exhibit, provided that exhibit and display opportunities at the event have also been provided by the event sponsor to other companies other than Bayer Animal Health.
 - If the program includes events which relate to an approved use of Bayer Animal Health products and the
 - Event sponsor has provided the opportunity to multiple companies to display at the event, Bayer Animal Health employees may display or exhibit at the program. For more information, see Policy and Procedure 8, “Product Exhibits and Displays.”

ACCEPTABLE EDUCATIONAL GRANTS

In summary, a grant is permitted only if:

- It is provided to foster increased understanding of scientific, clinical, or health care issues that contribute to the improvement of animal care; and
- It will be used solely for legitimate expenses related to education or training of veterinarians (and staff) in connection with medical education, training, or the improvement of animal care; and
- It is awarded to an organization and not an individual; and
- It is not awarded to an organization that is a private veterinarian practice group; and
- The organization, not Bayer Animal Health, controls the disbursement of the funds; and
- The responsibility for and control over the selection of content, faculty, educational methods, materials, and venues belongs to the organizers of the conference in accordance with their guidelines; and
- The grant is provided in response to a written request on the organization's letterhead, addressed to Bayer Animal Health, and signed by the organization that:
 - Describes the purpose/intended use of the grant or references other documents attached; such as a brochure, pamphlet, flyer, agenda, memo, or any other supporting documents; that describes the purpose/intended use of the grant. It is not acceptable to list only a generic description (e.g., "educational grant" or "training grant") as the purpose of the expense.
 - Confirms that the grant will be used for educational purposes.
 - Confirms that the grant will not be used for general overhead or for expenses of attendees.
 - Acknowledges that Bayer Animal Health may audit or review the use of the grant for compliance with guidelines for acceptable educational grants.
 - Confirms that Bayer Animal Health's funding and relationship with program provider, presenters, or moderator will be disclosed to attendees.

UNACCEPTABLE EDUCATION GRANTS

A grant is **NOT** permitted if it is any one of the following:

- Intended as a price term, or offered in lieu of a price concession; or
- Intended to encourage off-label use; or
- Contingent on the purchase of Bayer Animal Health products; or
- Intended to encourage the recipient to order, prescribe, or recommend Bayer Animal Health products or reward or compensate the recipient for so doing; or
- Made at the request of a veterinarian in his/her individual capacity (e.g., a request by a veterinarian to fund his/her “pet project”). It is acceptable for a veterinarian to request a grant in his/her official capacity, such as an officer of a veterinary medical association; or
- Made in return for anything of value provided to Bayer Animal Health by the recipient, with the exception of disclosure in program materials that the program is funded by Bayer Animal Health.

INVITATIONS FOR EXHIBIT SPACE AT THE EDUCATIONAL EVENT

It is not appropriate to receive exhibit space or advertising space in return for an educational grant. Generally, it is Bayer Animal Health’s practice to request a separate invoice for exhibit fees; however, circumstances may be such that there is no meaningful separation of exhibit fee in the documentation submitted by the requesting organization. It is common for the requesting organization’s documentation to extend an invitation for exhibit space at an associated event along with an educational grant. In these situations, it may be necessary to submit only one payment request with the total dollar amount covering both the exhibit space and the educational grant funds. For more information, see Policy and Procedure 8, “Product Exhibits and Displays.”

RECORD RETENTION

The Law and Patents Department maintains copies of all contracts and supporting documentation surrounding the CE program for a period of time as required by law or the Corporate Record Retention Policy.

The Accounting Department must maintain copies of all vendor invoices and payment details for a period of time as required by law or the Corporate Record Retention Policy.

AUDIT

All education grants and CE programs are subject to audit by Corporate Audit and HealthCare Compliance to ensure compliance with these policies. The government (e.g., IRS) may also request to audit/review educational grant payments.

10. FEE-FOR-SERVICE ARRANGEMENTS

This policy allows Bayer Animal Health to enter into certain relationships, or fee-for-service arrangements, with veterinarians provided certain criteria are met. Arrangements to reimburse individuals for speaking engagements, consultancies or participation on advisory boards should never be used to encourage the recipients to purchase or use Bayer Animal Health products nor should these arrangements be used to reward “high prescriber.”

CLARIFICATION OF TERMINOLOGY AND PROGRAMS

Advertising space in newsletters or other printed materials produced by customers or industry groups, whether or not they are contracted through a third-party such as an advertising agency, are not “fee-for-service” arrangements and the Corporate U.S. Signature Authorization Policy 002.20130115 applies. Payment for advertising space must not be contingent on, or used as a reward for, the purchase, prescription or recommendation of any Bayer Animal Health products. Modest sponsorship acknowledgement in printed materials associated with Bayer Animal Health payments for educational grants and charitable contributions is acceptable without separate authorization.

Advisory Board meetings must be to gain expert feedback or advice on commercial or clinical/medical topics -- not to provide a forum for product promotion. Bayer Animal Health representatives should ensure that advisory board participants clearly understand that they are being retained to provide a service and not merely to passively receive promotional presentations. An advisory board meeting cannot be designed to (1) influence the invited consultants or to change their prescribing preferences; (2) provide participants with an opportunity to meet and mingle with their peers; or (3) have participants merely listen to new information about Bayer Animal Health products.

Consultants are generally veterinarians paid by Bayer Animal Health to provide the Company important and needed information about its products, sales, marketing practices, and related issues (e.g., disease states).

Fee-for-service transactions include, but are not limited to, speaker agreements, consultant agreements, advisory board participation, and related activities where individuals (or the companies that employ them) are reimbursed for services rendered. Payments to organizations or entities other than employers of the individual providing the service are not fee-for-service arrangements and must be paid pursuant to other applicable policies.

Promotional speaker events include a spokesperson who are acting or speaking on Bayer Animal Health's behalf and the only topics of discussion are approved uses of Bayer Animal Health products. Bayer Animal Health employees may only control and influence the speaker or program content in cases when the only topics of discussion are approved uses of Bayer Animal Health products. The speaker may or may not be paid a fee for his/her services.

These events may or may not include a meal for all attendees. All speakers and materials used by speakers at Bayer Animal Health promotional events must be pre-approved by Bayer Animal Health. The presenter and materials must clearly identify that Bayer Animal Health is sponsoring the presentation, the fact that the speaker is presenting on behalf of Bayer Animal Health, and that the speaker is presenting information that is consistent with FDA, EPA or FTC guidelines. A Bayer Animal Health representative must attend each program.

Topics must address approved uses of Bayer Animal Health products and be of a scientific or medical nature. Speaker programs topics such as "Retirement Planning," "Practice Management" or "Golf Tips" are not permitted.

The location of a speaker event must be conducive to the exchange of information and to the presentation format planned for the program. Locations that are, by their nature, entertainment (such as a dinner riverboat cruise) are not appropriate.

Speakers for CE programs are controlled by an independent third party or under appropriate guidelines pursuant to RACE or other accredited CE certification. Speakers for CE programs are not covered under fee-for-service arrangements discussed in this procedure and need to be processed and approved according to Policy and Procedure 9, "Education Grants (Including Continuing Education)," in this booklet.

PERMISSIBLE FEE-FOR-SERVICE AGREEMENTS

Fee-for-service arrangements are permitted if ALL of the following are true:

- A **legitimate need** for the services has been clearly identified in advance of requesting the service and documented by a contract.
- Compensation paid represents **fair market value** for the services rendered.
- The speakers or consultants are chosen based upon relevant qualifications, experience and expertise as well as the value their services would provide to Bayer Animal Health, not based on volume or value of business generated by the speaker or consultant. Sales personnel may not be involved in selecting members of the speaker bureau or engaging healthcare professionals to serve as consultants. Those responsible for selecting the speaker or consultant must have the expertise necessary to evaluate whether the healthcare professional has the required qualifications.

- The venue and circumstances of meetings with consultants must be conducive to the consulting services, and activities related to the services must be the primary focus of the meeting. Exotic and/or resort locales are prohibited. Bayer Animal Health may provide modest entertainment or recreational activities to veterinarians in connection with a consultant meeting or advisory board meeting. However, the amount of time spent on entertainment must be *clearly subordinate* to the amount of time spent on the purpose of the event.
- Consultant meetings and advisory board meetings must be approved by the Legal Department **before** invitations may be sent and **before** venues may be booked.
- The number of participants, speakers, advisors and/or consultants chosen is consistent with the business need.
- The written contract must specify the nature of the services and the basis of payment for those services. The contract must be approved by the Law and Patents Department before it is signed by the speaker or consultant and Bayer Animal Health. No Bayer Animal Health employee may execute any contract or other legally binding document without review and approval from the Law and Patents Department. If a healthcare provider refuses to sign the agreement provided by the Law and Patents Department prior to the initiation of the program, he or she cannot be retained to provide the service.

CONTENTS OF THE CONTRACT

Bayer Animal Health may offer reasonable compensation (e.g., speaker fee, consultant fees) for the services performed. Reasonable is determined based on the fair market value of the services of the speaker or consultant, based on his or her experience and expertise as well as the time committed. All individuals who approve a fee-for-service arrangement must review the proposal to ensure the fair market value of the transaction. The Law and Patents Department makes the final determination as to the reasonableness of the fair market value for the requested services.

A Bayer Animal Health employee must be present or otherwise confirm that the services purchased were satisfactorily received before payment is generated. The Bayer Animal Health employee formally confirms proof of service by signing as the requestor. The contract must not prohibit Bayer Animal Health from witnessing the services rendered or otherwise obtaining proof of service.

The written contract may indicate that Bayer Animal Health will reimburse reasonable expenses incurred by the speaker or consultant in connection with the services provided to Bayer Animal Health, to include travel, lodging, and meals as described in the approved written contract. Bayer Animal Health must not reimburse incidental expenses, such as gift shop purchases. Bayer Animal Health may not pay for any expenses associated with the spouse or guest of a consultant, such as travel, meals or entertainment. A spouse or guest may share a hotel room with the consultant, provided Bayer Animal Health incurs no additional costs.

RECORD RETENTION

The Accounting Department will retain the full payment request package according to Procedures for a period as required by law or the Corporate Record Retention Policy.

AUDIT

All fee-for-service arrangements are subject to audit by Corporate Audit and HealthCare Compliance to ensure compliance with this Policy, including proper documentation, spending limits, and company spending policy. The government (e.g., IRS) may also request to audit/review all fee-for-service agreements. The Bayer Animal Health employee requesting the service or information must be prepared to demonstrate a legitimate business need for the program and demonstrate how information gleaned from the program was used.

11. CORPORATE SPONSORSHIPS

Bayer Animal Health may provide funds for sponsorships to various trade, medical, professional, patient, scientific and community organizations. The recipient organization's mission should be to increase understanding of scientific, clinical, or healthcare issues that contribute to the improvement of animal care or continuing education of professionals.

Sponsorship funds may not be paid to Bayer Animal Health customers except in limited circumstances, approved by Law and Patents, where the event is open to all members and provided the same opportunity is given to other similarly situated members.

Sponsorships may not be paid to encourage the recipient organization to purchase, order, refer, use or recommend Bayer Animal Health products. It is Bayer Animal Health's policy to pay the same fee as other corporate sponsors for the same level or type of sponsorship.

Sponsorship funding must not be used to reimburse the travel, lodging, or other personal expenses of attendees, to compensate attendees for their time, or to provide any type of gift to the attendees or presenters. Sponsorship funding also may not be provided on behalf of any customer, patient, or other individual.

Bayer Animal Health may provide general funding for a professional association's, patient or other organization's activities or meetings under appropriate circumstances. The recipient organization must have sole control over the funding paid by Bayer Animal Health. Sponsorship may be recognized by the organization, including the level of sponsorship provided (e.g., platinum, gold, silver) on its meeting brochures or banners, website, or other materials. Sponsorship of meetings or activities that will be attended primarily by veterinarians must be open to other companies in the industry.

It is important to determine whether a request for support is a charitable contribution, corporate sponsorship or educational grants. The terminology used by the entity requesting the funding (e.g., "charitable contribution," "grant") is not the determining factor because organizations may submit funding requests using inconsistent or incorrect terminology. The key factors are the type of entity requesting the funding (e.g., non-profit, patient organization, hospital) and focus of the event or activity (e.g., education or fundraising). For example:

- A **charitable contribution** is funding provided to a non-profit organization to support the organization's activities where Bayer Animal Health does not expect to receive anything in return and where the primary purpose of the event/activity is fundraising/charity.
- A **sponsorship** is funding provided to support the activities of an organization where Bayer Animal Health receives something of value, such as banners or

signage at a conference or an opportunity to advertise in the organization's publication. The sponsorship opportunity is offered to other similarly situated industry members and not just Bayer Animal Health.

- An **education grant** is funding provided to support an event where the primary focus is educating the participants/attendees, rather than fundraising.

Key Characteristics: Charitable Contributions vs. Corporate Sponsorships vs. Education Grant

Characteristics	Charitable Contributions	Corporate Sponsorships	Education Grants
Promotional in nature	No	Yes	No
Payee must be a 501(c)(3) or other tax exempt organization	Yes	No	No
Bayer HealthCare receives something of value in return	No	Yes	No
Payment can be made to an individual HCP or private practice group	No	No	No
Tickets or invitations received as a result can be offered to veterinarians or other customers	No	No	No
Sales and Marketing Involvement	No	Yes	No

Examples of Permissible Sponsorships

- "Gold" level annual sponsorship of the American Heartworm Society for general educational programs regarding heartworm prevention and awareness
- Sponsorship funding of appropriate, non-educational activities, such as a modest hospitality suite at national meetings of medical societies or organizations, such as American Veterinary Medical Association (AVMA) or the National Cattlemen's Beef Association (NCBA) or a Wi-Fi Café during medical society meetings
- Accepting a seat on an advisory council to the Companion Animal Parasite Counsel, if this benefit is also provided to other animal health companies who provide a similar level of sponsorship

Examples of Impermissible Sponsorships

- Sponsorship of a hospitality suite at a disease-state awareness program sponsored by the Western Veterinary Conference that is intended specifically for a discussion of a disease state for which Bayer Animal Health products are not indicated.

Requirements

The recipient organization receiving Bayer Animal Health sponsorship funds must support or conduct activities related to healthcare, scientific, or clinical issues that contribute to the improvement of animal care, education, or advocacy. Under no circumstances may sponsorship funds be offered or provided with the intent to, directly or indirectly, encourage the recipient organization to purchase, order, refer, use or recommend Bayer Animal Health products, or to reward any recipient organization for a past purchase, prescription or recommendation of a Bayer Animal Health product or service. Payment of sponsorship funds may also not be used to provide a direct or indirect discount on product purchases or to influence any recipient's conduct or decisions in connection with clinical or other research or the dissemination of medical or scientific data.

PROCEDURES

Requestor

A medical or professional society or other organization may solicit sponsorship through a website, e-mail, or paper mailing. No Bayer Animal Health employee may commit the Company to funding a sponsorship request without review and approval in accordance with this policy. All requests for sponsorship must be made in writing from the requesting organization on its letterhead and must include a completed W-9 form. The request must specify:

- The purpose of the request;
- The types of sponsorship opportunities available and the cost(s) thereof;
- The name and address to which the check must be payable;
- The Federal Tax ID number of the payee; and
- Whether the organization is affiliated with a Bayer Animal Health customer.

Law and Patents Review

The Law and Patents Department reviews all documentation and makes an independent judgment as to whether the requested fees are reasonable and the request is consistent with Bayer Animal Health's policies. If appropriate, the Law and Patents Department approves the request.

RECORD RETENTION

The recipient of the request for sponsorship will retain the request documentation and all proof of service documents for a period of 10 years.

AUDIT

All requests for sponsorship are subject to auditing by Corporate Audit and HealthCare Compliance to ensure compliance with this policy. The government (e.g., IRS) may also request to audit/review sponsorship payments.

12. CHARITABLE CONTRIBUTIONS (OTHER THAN FREE BAYER PRODUCTS)

Bayer Animal Health provides legitimate charitable contributions to support medical research, animal health initiatives, public education, community organizations within a Bayer Animal Health business community and other charitable events that directly benefit animals. This policy is designed to enable Bayer Animal Health and its employees to provide legitimate charitable contributions in a manner that does not create an appearance of impropriety.

SCOPE

A charitable contribution is anything, other than free products, provided to an IRS tax-exempt charitable organization, for which Bayer Animal Health does not receive anything of value in return. Charitable contributions include, but are not limited to, cash or cash equivalents (e.g., checks, gift certificates) and items contributed for raffles or other fundraising efforts (e.g., Bayer logo items, golf clubs, event tickets, etc.).

This policy does not cover the provision of free Bayer Animal Health product for charitable causes.

It is important to determine whether a request for funding support should be processed as a charitable contribution, corporate sponsorship or educational grant. The terminology used by the entity requesting the funding (e.g., "charitable contribution," "grant") is not the determining factor because organizations may submit funding requests using inconsistent or incorrect terminology. The key factors are the type of entity requesting the funding (e.g., non-profit, patient organization, hospital) and focus of the event or activity (e.g., education or fundraising).

- A **charitable contribution** is funding provided to a non-profit organization to support the organization's activities where Bayer Animal Health does not expect to receive anything in return and where the primary purpose of the event/activity is fundraising/charity rather than education.
- A **sponsorship** is funding provided to support the activities of a professional, medical or patient association or organization where Bayer Animal Health receives something of value, such as banners or signage at a conference or an opportunity to advertise in the organization's publication
- An **education grant** is funding provided to support an event where the primary focus is educating the participants/attendees, rather than fundraising.

The Company spending policy is designed to allow Bayer to take advantage of appropriate IRS tax deductions.

Key Characteristics: Charitable Contributions vs. Corporate Sponsorships vs. Education Grant

Characteristics	Charitable Contributions	Corporate Sponsorships	Education Grants
Promotional in nature	No	Yes	No
Payee must be a 501(c)(3) or other tax exempt organization	Yes	No	No
Bayer HealthCare receives something of value in return	No	Yes	No
Payment can be made to an individual HCP or private practice group	No	No	No
Tickets or invitations received as a result can be offered to veterinarians or other customers	No	No	No
Sales and Marketing Involvement	No	Yes	No

Bayer Animal Health will not make charitable donations to individuals, political parties or causes, or religious groups for religious purposes. In addition, it is Bayer Animal Health policy not to provide charitable donations to Bayer Animal Health customers or private practice groups, or to non-profit entities controlled by or affiliated with Bayer Animal Health customers or private practice groups.

EXCLUSION OF SALES AND MARKETING PERSONNEL

Under no circumstances may Sales or Marketing personnel engage in discussions, negotiations or unsolicited requests with an organization for the support of medical research, indigent care, patient education, public education, community organizations within a Bayer Animal Health business community and other charitable events that directly benefit animals which are all considered charitable contributions under Bayer Animal Health's Compliance Policies and Procedures. The Contribution Review Committee is responsible for the review and approval of all Charitable Contributions. In addition, Sales and Marketing may not be included in any communication regarding status of a request. If Sales or Marketing is approached by an organization regarding a charitable contribution, they are to direct the organization to the website: <http://grants-contributions.bayerweb.com/en/home/>.

REQUIREMENTS

Charitable contributions are permitted only if they meet the following requirements:

- The contribution is intended solely for charitable purposes. Bayer Animal Health receives nothing of value in return other than an acknowledgement of Bayer Animal Health's sponsorship by the charitable organization.
- The recipient is a qualified 501(c)(3) tax-exempt organization or otherwise IRS tax-exempt charitable organization that is not a Bayer Animal Health customer or physician practice group, or an organization controlled by or affiliated with a Bayer Animal Health customer or physician practice group, except in the limited circumstances referenced above. A tax exempt letter is required for submission of a charitable contribution
- It is generally Bayer Animal Health's practice to return tickets received in return for a charitable donation to the charity.

Corporate membership fees to medical organizations are not charitable contributions and must comply with Policy and Procedure 6, "Corporate Memberships," in this booklet.

A charitable contribution is NOT permitted if it is any of the following:

- Intended as a price term or offered in place of a price concession.
- Contingent on the purchase of any Bayer Animal Health products.
- Intended to encourage the recipient to order, prescribe, or recommend Bayer Animal Health products or to reward the recipient for ordering, prescribing, or recommending Bayer Animal Health products.
- Intended as payment for services or goods.
- Provides a benefit to Bayer Animal Health.

If you receive a request for a charitable contribution that is prohibited under Bayer Animal Health's policies, you should inform the person making the request that Bayer Animal Health's policies prohibit making the contribution. Any questions regarding charitable contributions should be addressed to your supervisor or the Law and Patents Department.

Invitations for Exhibit Space at the Charity Event

It is not appropriate to receive exhibit space or advertising space in return for a charitable contribution. Generally, it is Bayer Animal Health's practice to request a separate invoice for exhibit fees. However, circumstances may be such that there is no meaningful separation of exhibit fee in the documentation submitted by the requesting organization. It is common for an organization to extend an invitation for exhibit space at an associated event in their written request document for an educational grant or charitable contribution. In these situations, the Charitable Contribution Review Committee will determine whether the contribution will be approved and/or whether Bayer Animal Health may display at the event.

PROCEDURES

Requestor

All Charitable Contribution requests must be submitted electronically by the requestor through the Bayer website: <http://grants-contributions.bayerweb.com/en/home/>. The requestor (or institution-designated staff member) shall electronically input all required charitable contribution information and attach a copy of the requestor's organization 501(c)(3) letter, indicating its status as a tax-exempt charitable organization. Additional backup documentation (e.g., agenda, budget) may also be required. The requestor is responsible for providing all Charitable Contribution related documentation.

Under NO circumstances will a charitable contribution request be accepted after the event has occurred.

The Requestor may call the Public Policy and Government Affairs Department with any related questions and/or for confirmation of the status of the organization.

Contribution Manager

The Charitable Contribution request will first be reviewed by the Contribution Manager. If the request is deemed to be complete, within budget and strategic plan, it will be placed on a schedule to be reviewed and approved by the Charitable Contribution Review Committee.

If the Contribution Manager, after attempts to obtain appropriate documentation, finds the request incomplete he/she will inform the requestor of the denial of request.

Charitable Contribution Review Committee

The Charitable Contribution Review Committee ("Review Committee") is comprised of members from Veterinary Technical Services ("Medical Affairs"), Public Policy and Government Affairs, and Law and Patents. Sales and Marketing personnel do not participate in the Contribution Review Committee; however, they may provide a strategic plan relating to the subject matter of contributions to be considered.

The Review Committee reviews Charitable Contribution Requests from a regulatory and legal perspective consistent with the following objectives:

- Each Committee member certifies that there are no legal or compliance issues that would prohibit Bayer Animal Health's approval of the contribution request (e.g., no conflict with government or industry guidelines or Compliance Policies and Procedures).
- Approval of request is based on the support of medical research, patient education, indigent care, public education, and other charitable activities that benefit animals.
- The request for support is within the budget.
- The request for support is aligned with Bayer Animal Health's strategy, community, and therapeutic focus.
- The request will be used solely for charitable purposes and Bayer Animal Health receives nothing of value in return.

Upon review of the Charitable Contribution requests, the Review Committee may request that additional questions be answered prior to consideration of the Charitable Contribution request. For each such Charitable Contribution request, the Review Committee will approve or decline in conformance with these Compliance Policies and Procedures. If the Law and Patents representative is not present, Law and Patents must review the charitable contribution before it is approved.

Contribution Manager Post Approval Documentation

A letter documenting the Review Committee's decision will be provided to the requestor (or institution-designated staff member).

The Contribution Manager is responsible for updating the electronic system with the decision.

RECORD RETENTION

The Public Policy and Government Affairs Department will retain the payment request package for a period of time as required by law or the Corporate Record Retention Policy.

AUDITS

All charitable contributions are subject to audit by Corporate Audit and HealthCare Compliance to ensure compliance with these policies. The government (e.g., IRS) may also request to audit/review charitable contributions.

13. APPROPRIATE TARGET AUDIENCE FOR PROMOTIONAL ACTIVITIES

Promotion of Bayer Animal Health prescription products is directed to veterinarians (and their staff). Sales representatives may make calls or present product information only in situations in which the audience is comprised, to a reasonable degree, of veterinarians who have reason to prescribe, administer or dispense Bayer Animal Health prescription products for approved uses.

ADDITIONAL GUIDANCE

Audiences for promotional activities should not be selected in such a way as to circumvent the prohibition on promotion of Bayer Animal Health prescription products for unapproved uses.

For example, Bayer Animal Health representatives cannot:

- Make sales calls, present product information, or provide samples to veterinarians who specialize in disease states that are not aligned with the approved use of a Bayer Animal Health product.
- Display or hand out literature and/or free product samples at a convention or conference dealing primarily with off-label topics.
- Host a speaker program for veterinarians whose practice does not include any on-label uses of a Bayer Animal Health product.

Questions regarding the approved use of the products must be directed to Medical.

14. APPLICATION OF PROMOTIONAL POLICIES OUTSIDE THE US

If Bayer Animal Health products are being promoted for use in the United States – even if that promotional activity takes place outside the United States – these Compliance Policies and Procedures, as well as the Bayer HealthCare Code of Conduct, apply.

ADDITIONAL GUIDANCE

- You may not discuss off-label uses of a Bayer Animal Health product with a U.S. veterinarian, or offer prohibited remuneration, simply because you are both attending a conference outside the United States. Use extra care in setting up courtesy suites or exhibit booths abroad. If the product will be used in the United States, you are bound by United States promotional rules.
- Bayer Animal Health personnel cannot arrange for the attendance of U.S. veterinarians at medical education programs outside the U.S. to discuss uses unapproved in the U.S., even if those uses are approved in the country where the medical education program takes place.
- Policies related to unlawful remuneration or kickbacks apply when you are overseas interacting with U.S. customers and/or veterinarians.
- Bayer Animal Health personnel must adhere to applicable international industry guidelines when interacting with international veterinarians who may prescribe, recommend, purchase or lease Bayer Animal Health products.
- The US meal and travel policies must be followed when interacting with a US veterinarian who is outside the US. Please refer to Policy and Procedure “Business Meals and Entertainment with HealthCare Professionals.”

15. MATERIALS FOR EXTERNAL USE

Bayer Animal Health employees, contractors, consultants and agents may only distribute promotional and non-promotional materials that are approved through the Legal, Medical, and Regulatory - Marketing Material Review Committee (LMRC).

Bayer Animal Health employees, contractors, consultants and agents may conduct presentations to instruct veterinarians on the proper, on-label use of Bayer Animal Health products. However, you must neither solicit questions about nor provide presentations for unapproved uses. You may not make suggestions about, or assist in, specific prescribing decisions.

ADVERTISING AND PROMOTIONAL MATERIALS

Advertising and promotional materials include but are not limited to visual aids, file cards, journal article reprints, journal supplements, article abstracts, pilot study reports, letters to veterinarians, audiovisual materials, slide or computer presentations, displays, computer programs and Internet or Internet-based programs and websites.

SELF-CREATED MATERIALS ("HOMEMADE BREAD")

Creating your own promotional materials – also known as “homemade bread” – IS STRICTLY PROHIBITED. Self-created materials not only includes detailing pieces, but also include publically available materials (websites, journals, press releases) and documents containing cost comparisons, reimbursement information or other materials that have not been approved through the LMRC process.

Adding to, altering or modifying approved promotional or non-promotional materials, such as by highlighting, deleting, editing or adding notes or other material, makes those materials unacceptable for use.

Any changes to approved materials or changes in the contextual use of materials must be resubmitted for approval by the LMRC review process.

NON-PROMOTIONAL EDUCATION MATERIALS

Educational or business materials that are used for advisory boards, investigator meetings, speaker training, etc., may not be distributed to veterinarians who do not attend the meeting. All such materials must be approved through LMRC prior to distribution or use at these meetings.

COMPARATIVE CLAIMS

You may not make comparative or superiority claims without substantial clinical evidence (e.g., generally two or more well run and statistically significant studies) as provided in approved materials. Do not compare product reactions/events from package inserts of other Bayer Animal Health products or of competitor's products.

REQUESTS FOR NON-APPROVED MATERIALS

Requests from veterinarians or other Bayer Animal Health customers for materials discussing off-label uses must be directed to the Director of Veterinary Services. Do not solicit requests or inquiries for off-label uses. Requests for materials that are not approved for promotion must be directed to the Marketing Department to initiate the review and approval process by the Marketing Material Review Committee (consisting of members from Legal, Regulatory, Veterinary Services, and Marketing).

16. MATERIALS FOR INTERNAL USE ONLY

Bayer Animal Health permits the distribution among its employees, contractors, consultants and agents of certain educational materials that are intended for education or to provide general business information. These materials may not; however, be used externally (e.g., to promote, discuss or reference Bayer Animal Health products), unless approved for such use.

COMMUNICATIONS AND MATERIALS TO SALES FORCE

Educational or business materials that are to be used for internal purposes only must be clearly marked with language such as **"STOP: For your educational use only, confidential and proprietary information, not to be distributed externally."** It is the obligation of every Bayer Animal Health employee, contractor, consultant and agent providing services to or on behalf of Bayer Animal Health distributing such material to ensure that the material is clearly marked in this manner, including when forwarded by electronic mail. Documents that are provided only for internal use (e.g., for your information only) are not to be distributed to or discussed with customers.

SHARING OF INFORMATION GATHERED FROM PUBLICLY AVAILABLE SOURCES FOR EDUCATIONAL PURPOSES (IN ACCORDANCE WITH COPYRIGHT RESTRICTIONS)

Subject to the process below, information gathered from the public domain may be shared among Bayer Animal Health employees, contractors, consultants and agents (e.g., within the sales force, from representative to representative, representative to manager, or manager to representative). Examples of industry related information gathered from the public domain would include:

- Competitive intelligence (e.g., revised package inserts for competitive products, press releases regarding new data or studies on competitive products);
- Industry or product related news or information from the lay press (newspapers, magazines, on-line news services, Pink Sheet, industry publications, medical journals, medical text books);
- Consumer advertisements (e.g., newspaper ad) :and
- Recall notes.

If a Bayer Animal Health representative or manager shares information gathered from the public domain, he/she cannot interpret or analyze the information in any way.

The party forwarding the information must include a disclaimer such as:

"STOP: For your educational use only. Not to be used as a promotional item."

Information gathered from the public domain must be forwarded to marketing and sales training for LMRC review before it is disseminated. The LMRCs will formulate appropriate educational materials for the field as needed.

17. OPEN

18. REVIEW OF COMPLIANCE TEXT MATERIALS

Bayer HealthCare is committed to appropriate and timely communications to all HealthCare Compliance Program employees, contractors, consultants and agents regarding significant changes in the Bayer Animal Health Compliance Policies and Procedures ("Compliance Policies and Procedures") and the Bayer HealthCare Code of Conduct ("Code of Conduct") materials.

Annually (or more often as necessary), Bayer HealthCare will review the Code of Conduct, Compliance Policies and Procedures and the Compliance training texts to determine if revisions are appropriate and makes any necessary revisions based on such review.

Code of Conduct revisions are distributed to all Bayer HealthCare employees, contractors, consultants and agents within thirty days of finalizing such changes. Bayer HealthCare employees, contractors, consultants and agents must certify that they have received, read, understood and will abide by the revised Code of Conduct within thirty days after distribution of revisions.

The relevant portions of any revised Compliance Policies and Procedures are distributed to all HealthCare Compliance Program employees, contractors, consultants and agents whose job functions are related to the revised Policies and Procedures within thirty days of the effective date of the revision.

The compliance training programs are updated as necessary and/or as a result of the text reviews.

19. OPERATING THE CONFIDENTIAL DISCLOSURE PROGRAM

The Bayer HealthCare Confidential Disclosure Program allows employees, contractors, consultants and agents to disclose, confidentially and without retaliation, any issues or questions associated with Bayer HealthCare's policies, practices, or procedures with respect to any federal health care programs believed by the individual in good faith to be a potential violation of criminal, civil or administrative law. The Confidential Disclosure Program is the Bayer IntegrityLine, a toll-free telephone line administered by a third party vendor, Global Compliance Services, Inc.

Global Compliance Services provides service twenty-four hours per day, seven days per week. Global Compliance Services will prepare reports of all disclosure calls. Each report will be assigned a Report Control Number and a PIN code, which will be provided to the caller. Callers may be provided a date on which to make a follow-up call for the purpose of receiving a response from Bayer or for the caller to provide additional information. The reports will be transmitted to the Bayer HealthCare Compliance Officer (or designee) within 24 hours of receipt.

Global Compliance Services checks reports received for "Special Handling". In this process, the parties named within a report are checked with the names of the designated report recipients (the Bayer HealthCare Compliance Officer or designee). If the same name appears on both lists, the report is marked for "Special Handling" and the person named in the report will not receive a copy of that report. If all designated report recipients (the Bayer HealthCare Compliance Officer or designee) are named within a report, the report will go to the Special Handling Report Recipient, who is the General Counsel & Sr. Vice President for Bayer HealthCare.

PUBLICATION OF CONFIDENTIAL DISCLOSURE PROGRAM

Information about the Bayer IntegrityLine is advertised to all Bayer HealthCare employees, contractors, consultants and agents. The following information will generally be included in the notice:

- The toll-free telephone number.
- The fact that the caller need not disclose his/her identity.
- The fact that the Bayer IntegrityLine should be used to report issues or questions associated with Bayer's policies, practices, or procedures with respect to any federal health care programs believed by the individual to be a potential violation of criminal, civil or administrative law.

- Reports may be made confidentially and without retaliation for reporting to the Bayer IntegrityLine.

THE CONFIDENTIAL DISCLOSURE LOG

Global Compliance Services, Inc. provides two reports to Bayer HealthCare Compliance each month; one summarizes reporting activity from the prior month and the other lists all open reports. Global Compliance Services, Inc. assigns the Report Control Number to each report which is recorded on all documents that are added to the disclosure file, as well as those that are maintained in the Human Resource and/or Law and Patents Department. This allows the status of any subsequent investigation to be tracked. The reports from Global Compliance Services, Inc. include all disclosures made to the Bayer IntegrityLine. Reports involving federal healthcare programs and/or Bayer Animal Health Compliance Policies and Procedures will be processed as described below and included in the Annual Report to the OIG. Reports that do not involve federal healthcare programs or Bayer Animal Health's Compliance Policies and Procedures, such as those involving employment or human resources issues, will be directed to the Law and Patents Department or the Human Resources Department within the related Bayer HealthCare business.

PROCEDURE UPON RECEIPT OF DISCLOSURE REPORT

Upon receipt of a disclosure report, the Bayer HealthCare Compliance Officer (or designee) makes a preliminary good faith inquiry into the allegations set forth in the disclosure to ensure that he or she has obtained all of the information necessary to determine whether further review should be conducted.

An internal review is initiated to investigate any disclosure that is sufficiently specific so that it reasonably permits a determination of the appropriateness of the alleged improper practice and provides an opportunity for taking corrective action. The Compliance Officer or Manager initiates the investigation by providing a summary of the allegation, including the Report Control Number, to the Law and Patents Department and/or the applicable Human Resource Department, as appropriate.

By the follow up date, Bayer HealthCare Compliance Officer (or designee) will provide a statement of closure or a request for additional information to Global Compliance Services to be provided to the caller. Once all necessary information is obtained and the investigation is finalized the disclosure report will be documented as closed by Global Compliance Services, Inc.

A final written report is maintained in the Bayer HealthCare Compliance Department and will include, as appropriate, the results of the investigation and corrective actions taken.

Corrective actions may include, but are not limited to, the following:

- Modifications to appropriate policies or procedures.
- Additional or remedial training.
- Disciplinary action, up to and including termination.

20. DISCIPLINARY ACTION

GENERAL RULE

Bayer Animal Health takes seriously all violations of (1) applicable federal, state or local laws or regulations, (2) applicable industry guidelines, and (3) the Bayer HealthCare Code of Conduct and Animal Health Compliance Policies and Procedures. Disciplinary action up to and including termination of employment may be taken against any Bayer employee, contractor, consultant or agent who violates applicable federal, state or local laws or regulations, industry guidelines, the Bayer HealthCare Code of Conduct, or the Animal Health Compliance Policies and Procedures.

NON-RETALIATION

Bayer Animal Health will not retaliate, or tolerate retaliation, against any Bayer Animal Health employees, contractors, consultants or agents for reporting in good faith any alleged compliance issue or other inappropriate activity involving applicable national, state or local laws or regulations, industry guidelines, the Bayer HealthCare Code of Conduct or the Animal Health Compliance Policies and Procedures.

DISCIPLINARY ACTION, TERMINATION AND REFERRAL TO LAW ENFORCEMENT

Bayer Animal Health employees, contractors, consultants or agents who violate applicable federal, state or local laws or regulations, industry guidelines, the Bayer HealthCare Code of Conduct or the Animal Health Compliance Policies and Procedures may be subject to disciplinary action up to and including termination of employment or other contractual arrangement. Any disciplinary action taken by Bayer Animal Health in response to a violation of the Animal Health Compliance Policies and Procedures should be commensurate with the severity of the violation, as determined in Bayer Animal Health's sole discretion. In the case of material violations of federal, state or local laws or regulations, it may be necessary to refer the compliance matter to appropriate law enforcement officials.

BAYER ANIMAL HEALTH EMPLOYEES CONTRACTORS, CONSULTANTS AND AGENTS, SUBJECT TO DISCIPLINARY ACTION

Disciplinary action may be taken against any Bayer Animal Health employee, contractor, consultant or agent who: (1) authorizes or participates in a violation of any applicable federal, state or local law or regulation, industry guidelines or the Animal Health Compliance Policies and Procedures; (2) knowingly withholds relevant and material information concerning an actual or suspected compliance issue or other inappropriate activity; or (3) fails to cooperate with an investigation by the Bayer HealthCare Compliance Officer or the Law and Patents Department.

Any Bayer Animal Health employee, contractor, consultant or agent who fails to report an actual or suspected compliance issue or other inappropriate activity that has been brought to his or her attention may be subject to disciplinary action, up to and including termination of employment.

21. INTERACTIONS WITH GOVERNMENT INVESTIGATORS

GENERAL RULE

Bayer Animal Health may be contacted or receive requests for information from various government agencies such as, for example, the Food and Drug Administration (FDA), the Department of Health and Human Services (including the Office of Inspector General (OIG)), Federal Bureau of Investigation (FBI), or other regulatory agency. It is Bayer Animal Health policy to cooperate fully with national and/or state government officials or agents who conduct an inquiry, audit or otherwise investigate Bayer Animal Health. Bayer Animal Health expects all employees, contractors, consultants, distributors, agents, and sales associates to extend the same cooperation within the guidelines of this policy.

REPORTING GOVERNMENT INQUIRIES OR AUDITS

All Bayer Animal Health employees, contractors, consultants and agents must immediately report to the Law and Patents Department any notice of a government inquiry or audit with respect to Bayer Animal Health related activities. Notice of a government inquiry may include, but is not limited to: (1) telephone calls or letters from government officials or agents to Bayer Animal Health employees, contractors, consultants and agents, (2) presentation of search warrants, (3) on-site visits to or inspections of Bayer Animal Health's premises by government officials or agents, or (4) visits by government officials to the homes of Bayer Animal Health employees, contractors, consultants and agents.

CONTACT BY GOVERNMENT INVESTIGATOR

In the event a Bayer Animal Health employee, contractor, consultant or agent is contacted by a federal or state investigator with respect to Bayer Animal Health activities, the employee, contractor, consultant or agent must obtain proper identification from the government investigator prior to answering questions. Bayer Animal Health employees, contractors, consultants and agents: (1) are not required to answer any questions asked by the government agent without assistance of the Law and Patents Department, (2) have the right to decide whether or not to consent to an interview, (3) have the right to consult legal counsel – either their own or Bayer Animal Health counsel – before answering any questions and to have such counsel present during questioning by a government agent, and (4) may stop the interview at any time.

If a government investigator attempts to contact or interview a Bayer Animal Health employee, contractor, consultant or agent at his or her respective home and/or any location which is off Bayer Animal Health premises with respect to Bayer Animal Health related activities, the employee, contractor, consultant or agent has the right to either: (1) talk to the government investigator, (2) not talk to the government investigator without representation by an attorney, or (3) request that an appointment be scheduled on Bayer Animal Health's

premises during regular business hours or at an alternate time and place that is otherwise convenient. If so requested by the employee, contractor, consultant or agent, Bayer Animal Health will have an attorney or other representative attend such interview.

GOVERNMENT INTERVIEWS

If a Bayer Animal Health employee, contractor, consultant or agent decides to be interviewed or to respond to questions from a government investigator with respect to Bayer Animal Health related activities, the employee, contractor, consultant or agent should answer all questions completely, accurately and truthfully. Bayer Animal Health employees, contractors, consultants or agents should not guess, speculate or make-up answers to questions to which the answers are not known with some degree of certainty.

In addition, if the employee, contractor, consultant or agent consents to an interview, the employee, contractor, consultant or agent must obtain specific authorization from the Law and Patents Department before discussing the company's privileged information. The employee, contractor, consultant or agent should refuse to discuss any communications he or she may have had, or of which he or she may be aware, involving the Law and Patents Department or Bayer's outside legal counsel. If the employee, contractor, consultant or agent does not know whether the information being asked to discuss is privileged, the employee, contractor, consultant or agent should consult with the Law and Patents Department for a determination as to whether that information is privileged to ensure that no unauthorized disclosures of privileged information are made.

If you do not know with certainty the answer to any question, it is appropriate to say that you do not know the answer to the question. If an employee, contractor, consultant or agent would like to consult with an attorney, the employee, contractor, consultant or agent may request the presence of Bayer Animal Health counsel. Alternatively, Bayer Animal Health counsel may recommend qualified external counsel and, under the appropriate circumstances, will pay for such counsel to represent the Bayer Animal Health employee, contractor, consultant or agent. If at any time, the employee contractor, consultant or agent feels uncomfortable or uncertain about whether to proceed, or if at any time the employee, contractor, consultant or agent feels the need to consult with his/her own attorney or a Bayer Animal Health attorney, the employee, contractor, consultant or agent may stop the interview or tell the investigator that he/she wishes to consult with counsel.

CORPORATE DOCUMENTS

Bayer Animal Health employees, contractors, consultants and agents should contact the Law and Patents Department if asked by a government investigator or anyone outside the company for Bayer Animal Health documents. Bayer Animal Health documents include

all documents, whether in paper format or electronically stored that are held or created in connection with your employment at Bayer Animal Health. For example, Bayer Animal Health documents may include, but are not limited to, any (1) files, (2) notes, (3) memoranda, (4) e-mails, (5) correspondence, (6) reports, (7) sales information, (8) marketing information, (9) financial information, (10) project plans, and (11) design documentation. Likewise, your computer itself is Bayer Animal Health property and is subject to this policy.

In addition, Bayer Animal Health employees, contractors, consultants and agents must not provide privileged Bayer Animal Health documents to the government or anyone outside the company without specific authorization from the Law and Patents Department. Privileged documents include any documents involving the Law and Patents Department or Bayer Animal Health's outside legal counsel. If the employee, contractor, consultant or agent does not know whether the documents being requested are privileged, the employee, contractor, consultant or agent should consult with the Law and Patents Department for a determination as to whether that information is privileged to ensure that no unauthorized disclosures of privileged information are made.

SIGNING DOCUMENTS

Bayer Animal Health employees, contractors, consultants or agents may be asked to sign an affidavit or other legal document as the company's representative during the course of an interview. Bayer Animal Health does not authorize you to sign or initial any such documents or statements as a Bayer Animal Health employee, contractor, consultant or agent unless expressly authorized by the Law and Patents Department. If a Bayer Animal Health employee, contractor, consultant or agent is asked to sign such a document, the employee, contractor, consultant or agent should decline to do so and inform the government investigator of Bayer Animal Health's policy.

22. ADVERSE EVENTS INVOLVING BAYER PRODUCTS

REPORTING REQUIREMENTS

Bayer Animal Health is required to report to FDA adverse drug experience information associated with the use of a drug manufactured and/or marketed by Bayer HealthCare LLC, Animal Health Division. If you become aware of an adverse drug experience involving a Bayer Animal Health product or adverse event information (for EPA regulated Bayer pesticide products), you must report this information as promptly as possible, within or no later than twenty-four (24) hours, to the Veterinary Technical Services Department at 1-800-422-9874.

WHAT TO REPORT

- You must report information about an adverse drug experience, which is any adverse event associated with the use of a drug in animals, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose or use of the drug in an off label manner in other species, whether accidental or intentional; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.
- You must report adverse drug experience information associated with the use of a drug manufactured and/or marketed by Bayer Animal Health, whether or not you consider the event to be related to the drug.

NOTE: You must provide as much detail as possible about the event so that the Pharmacovigilance Department can identify you as the initial reporter and can identify the patient, the Bayer HealthCare Animal Health product involved, and the adverse event.

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