




# GLOBAL INTERACTION WITH HEALTHCARE PROFESSIONALS POLICY

**Reference: GLAD-POL- 006**  
**Version number: 1.0**  
**Department: Global Legal Affairs Department**

Written by	Reviewed by	Approved by
Global Legal Affairs Department	Marc Robert Fernandes, General Counsel	Nicolas Besins, CEO Alexandre Besins, CEO
Effective date: 20 August 2025		Review type: annual

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## Foreword

### Healthcare Professionals and Besins Healthcare: empowering collaborative healthcare

The Besins Healthcare Group is committed to producing the highest quality hormone therapies for the patients who need them. To support this mission, it is important that we build ethical relationships with healthcare professionals (“HCPs”). We are committed to ensuring that patients and HCPs have access to scientifically sound, evidence-based information about our products.

Strong, collaborative relationships with HCPs affords us the opportunity to:

- Share information on the benefits and risks of our products to promote their appropriate use by patients,
- Offer scientific and educational resources,
- Support medical research and education, and
- Gather feedback and advice from medical experts on our products.

This policy establishes a framework to ensure that all engagements with healthcare professionals are conducted within a legal and ethical context, focusing on professional exchanges that serve the best interests of patients and contribute to the advancement of medicine. This policy outlines our Corporate approach to engaging with healthcare professionals when marketing our products.


## 1. Purpose

This policy outlines the ethical guidelines for interactions between Besins Healthcare and Healthcare professionals (HCPs) Corporately, emphasizing transparency, integrity, and mutual respect.

## 2. Definitions

Unless otherwise specified, the terms used herein shall have the following meaning.

“Healthcare Professionals (HCPs)”	means individuals authorized to prescribe, dispense, recommend, or administer pharmaceutical products.
“Corporate”	means the corporate organization of Besins Healthcare located at Headquarters or in designated corporate services affiliates.
“Corporate Promotional Material”	means any form of published content advertising Pharmaceutical Products and originating from a Corporate department (mostly in English or French).

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“Promotion”	means the activities facilitating the prescription, supply, or recommendation of pharmaceutical products.
“Pharmaceutical Product”	means the medications intended for human use in diagnosing, treating, or preventing diseases.
“Medical Institution”	means the organizations comprising healthcare professionals or conducting healthcare research.
“Promotional Material”	means any form of published content advertising pharmaceutical products.
“Web sites”	means any kind of static online publication which uses the internet as a vector of communication.
“Business Unit Managers”	means the individuals in charge of the conduct of the Business in a Region.
“Region/Regional”	means the organizational subdivision (which may or may not recover a geographical area) within commercial activities of the Besins Healthcare Group.
“Regional Promotional Material”	means any Promotional Material developed within a Region in a local language which is not English.


### 3. Stakeholders

All Business Unit Managers, Besins Healthcare Corporate Medical Department, Corporate Regulatory Department, Corporate Marketing Department, and Corporate or Regional employees involved in HCP interactions. Corporate Heads and Business Unit Managers ensure policy compliance at Corporate and regional levels, delegating implementation to the Corporate Legal Affairs Department.

### 4. Interpretation

The Besins Healthcare Compliance Committee (the “Compliance Committee”) is ultimately responsible for providing guidance on the interpretation and implementation of this policy. Routine issues relating to interpretation or understanding of the policy may be referred to the Compliance Officer.

Each Region shall be obliged to implement and localize (translate and/or integrate local rules) this policy within three (3) months of its publication. Failing which, this policy shall directly apply in the Region as of December 1<sup>st</sup>, 2025.

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Regions are authorized to define stricter policies locally, and any stricter local laws, regulations or compliance policies shall prevail over this Policy in case of conflict.

## 5. Promotion

Any activity or interaction motivated by the objective of promoting products must be openly designated and considered as Promotion and be managed accordingly by Marketing Department. Activities and interactions conducted to foster scientific exchange or non-promotional medical education must be structured appropriately and managed accordingly by the Medical Department. There must be a strict division of roles with regards to these functions.

Activities and interactions purporting to receive information and advice or to obtain important scientific input or data, such as advisory boards and post-marketing studies, must not have the promotion of products as their purpose.

Non-promotional activities, such as advisory boards, market research, clinical studies, etc., must have as genuine objective to obtain the required, scientifically relevant and unbiased information and may never be designed in such a manner that it achieves promotional objectives, and generally must be conducted by Medical Department.

## 6. Promotional Materials, generally


All Corporate Promotional Materials undergo review by Medical Department and Regulatory Department to ensure alignment with local regulations and Corporate standards. Compliance monitoring is the responsibility of Corporate Departments Heads and Business Unit Managers. All documents created on Corporate Level (visual aids, advertisements, press releases, etc.) which can be used by regional offices for promotional purposes shall be reviewed and approved at Corporate Level prior to dissemination.

Corporate Regulatory Department and Corporate Medical Department must always be involved in the approval of Corporate promotional material to ensure compliance with regulatory and scientific requirements.

## 7. Promotional Materials, approval procedure

No Promotional Materials will be used that will not have undergone proper approval as defined in this section. Compliance with this section will be verified by the Compliance Officer via review of Form GLAD-F002/01, attached hereto. All Promotional Materials shall be developed in compliance with the applicable laws, codes of practices and this Policy or other policies or SOP as shall be developed and published within Besins Healthcare from time to time.

### 7.1. Approval of Corporate Promotional Materials


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### 7.1.1 Approval by Corporate Medical Affairs

- A. Any Promotional Materials or web site developed at a Corporate level shall always be sent by the Corporate Marketing department for review to the Corporate Medical Department (“CMD”). The CMD will designate an Officer (or Officers) in charge of the review of this material and shall advise the Compliance Committee of the identity of this or these Officer(s). Communication shall take place by electronic means whenever possible, with the Form GLAD-F002/01 properly completed. The Compliance Officer shall be copied on such correspondence.
- B. The CMD shall revert with its advice within fifteen (15) days of the receipt of said material. Should CMD find that the examination of the Promotional Material requires further examination, then it shall advise the requestor accordingly, and provide an updated timeline for review.
- C. If the CMD rejects the material, it shall specify the grounds for its decision or the modifications required for these materials to be compliant from a scientific and medical point of view.
- D. In the case of approval, the Officer in charge shall affix his signature on the said materials and send them back by electronic means with the Compliance Officer being copied. The original signed materials shall be kept at CMD for safekeeping.

### 7.1.2 Approval by Corporate Regulatory Affairs

- A. The Promotional Materials shall then be passed to the Global Pharmaceutical Affairs Department (GPA) The GPA shall designate an Officer (or Officers) in charge of the review of this material and shall advise the Compliance Committee of the identity of this or these Officer(s). Communication shall take place by electronic means whenever possible, with the Form GLAD-F002/01 properly completed. The Compliance Officer shall be copied on such correspondence.
- B. The GPA shall revert with its advice within fifteen (15) days of receipt of the said material. Should it find that the examination of the Promotional Material requires further delays for review, then it shall advise accordingly the department requiring the review, with a date for its advice.
- C. Should the GPA reject the materials, then it shall motivate its advice and advise on the modifications required for these materials to be compliant with the approvals for the product, or mention any regional/local restrictions on the use of these materials.
- D. In addition to the steps above, should Promotional Materials approved at Corporate level need to be used in a specific country, the Regulatory Officer in charge for the region will be required to approve these materials for compliance with local legislation prior to their usage,

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including approval by local authority where required. He will affix his signature on the materials to certify their compliance, under the responsibility of the Compliance Officer. Should no Regional Regulatory Officer be in place, then it will be the responsibility of the Region Head to ensure an appropriate review of the Promotional Materials in the Region from a local regulatory point of view prior to any usage.


- E. Should any Promotional Material fail to obtain approval at any of the stages above described, then it will have to reinitiate the process from start upon implementation of the modifications required.

### *7.1.3 Approval by Corporate Legal Affairs Department*

- A. Pursuant to the approval by all previous departments, then the Promotional Materials will be sent to GLAD for approval strictly on legal matters.
- B. The scope of the approval by GLAD shall be limited to usage of trademarks and IP matters, fraud and comparative publicity matters regarding the Promotional Materials in scope.
- C. The GLAD officer in charge of the review of these materials shall revert with his advice within fifteen (15) days of receipt. Should the GLAD Officer find that the examination of the Promotional Materials requires further delays for examination, then it shall advise accordingly the department requiring the review, with a date for its advice.
- D. Should the GLAD officer reject the materials, it shall motivate its advice and advise on the modifications required for these materials to be compliant with the approvals for the product, or mention any regional/local restrictions on the use of these materials.

### 7.2 Approval of Regional Promotional Materials

- A. Where Promotional Materials are developed for regional use, the Region Head is responsible for ensuring these Materials are systematically sent for review to the Regional Marketing Department, Regional Medical Department, and Regional Regulatory Department in that order. The procedure for the approvals of Regional Promotional Materials will replicate that described above under section 7.1 for Corporate Promotional Materials (the “Regional Approval Process”). These approvals will be required before using any Promotional Materials developed regionally.
- B. In any case, Corporate Marketing Department, Corporate Medical Department and Corporate Regulatory Department will need to be advised for information with a copy of the Promotional Materials (and an English translation) at the same time as a Regional Approval Process is initiated. This will not entail review and approval of Regional Materials but is an obligatory step prior to any diffusion of Regional Promotional Materials.

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- C. In case of major issue warranting intervention by any of the Corporate Departments mentioned in “C” above, then the required department shall be entitled to require suspension of the Regional Approval Process for a period not exceeding fifteen (15) days (the “Suspension Period”), by seizing the Compliance Officer (or in his absence, the General Counsel).
- D. The Compliance Officer will then initiate a review of the issues raised. The Compliance Officer will endeavour to assist Corporate Departments and Regions in finding a consensus within the respect of applicable rules.
- E. The Compliance Officer will also be entitled to extend the Suspension Period once by another fifteen (15) days at his discretion, to favour the research of a consensus.
- F. At the end of the Suspension Period, in case of a consensus, the Regional Approval Process will resume. Failing a consensus, the Regional Promotional Materials will be deemed rejected without further adjudication.
- G. The Regional Departments will be allowed to appeal the decision before the Compliance Committee.
- H. In case of absence of a Regional Regulatory officer or a Regional Medical officer for any Region, then the Region Head will be responsible for ensuring an appropriate review of the Regional Promotional Materials by seeking professional advice in order to comply with local regulations and this policy or such SOP or policies as shall be applicable within Besins Healthcare. The communication procedure foreseen under “B” above shall also be applicable. At any time, a Corporate Department may request suspension of the review process and advise the Compliance Officer accordingly, in which paragraphs “C” to “F” shall be applicable

## **8. Promotional Communications Content, generally**


All promotional content must be accurate, balanced, substantiated, and compliant with local regulations, with rigorous review processes in place. No Pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country (no “off-label” promotion).

## **9. Promotional Communications, standards.**

- A. Consistency of Product Information. It is understood that national laws and regulations dictate the format and content for the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material. Promotion should thus not be inconsistent with local approvals. In order to ensure this consistency, all Corporate materials will systematically undergo review by the Medical Department. In addition to this review, any Regional material must be approved by the Regional Regulatory and Regional Medical Department before release.


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- B. Accuracy. Any promotional content must present a clear, balanced and sufficiently complete view to enable the recipient to form his/her opinion of the therapeutic value of a product. It must be based on an up to date evaluation of the relevant evidence and not be false or misleading.
- C. Substantiation. Promotional content must be substantiated by reference to prescribing information as approved by regulatory authorities or additional scientific evidence meeting the requirements of regulatory authorities in the country where the promotional content will be used.
- D. General mentions to be affixed on Promotional Material. These requirements may be amended by specific local requirements. It is the duty of the Business Unit Manager to make sure the local requirements are satisfied before releasing such material.
1. Any promotional material (either printed or in electronic form) shall include in legible print size:
    - a) Trade name and generic name of the product;
    - b) Name logo and address of the company marketing the product;
    - c) Succinct statement (brief profile of the summary of product characteristics);
    - d) Date of production (month/year) together with a unique identifier.
  2. Abbreviated advertisements (viz., advertisements containing only a simple statement of indications and/or pharmacological class to designate the therapeutic category of the product must include:
    - a) Trade name and generic name of the product;
    - b) Name logo and address of the company marketing the product;
    - c) Note: “full prescribing information available from...”
  3. Websites. On web pages, appropriate measures should be taken to ensure that access is reserved to targeted audiences. It is forbidden to show actual HCP’s or patients on any promotional material without an explicit written authorization.
- E. Usage of Graphic visuals. Visuals must be accurate and consistent with the text, not contain misleading graphs, tables or artwork. Graphs and tables must be accurate and not misleading and they should include a description of the axes and must be accurately referenced. Misleading scales or dimensions must not be used.
- F. Use of unpublished data. The use of unpublished data is allowed, conditional to it being referred to as “data on file”. Any such data must be made available to HCP’s upon request. Therefore it should be kept available at the Corporate Medical Department before publication of the promotional material is undertaken, and must be kept for future reference. Publications or manuscripts accepted for publication or in press must be on hand in complete length, before the promotional material is printed.
- G. Requirements with reference to Claims. All claims must be consistent with the Core Data Sheet (in case of Corporate use) or the prescribing information as approved by the local regulatory authorities (in case of regional/local use). All claims must be true and substantiated or referenced from sources that can be readily made available upon request.

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One-sided information, or any conclusive statement based on inadequate or truncated evidence is not permitted. Superlatives, exaggerations, and hanging comparatives without unequivocal supporting data, which merely claim that “a product is better”, etc., must not be used by Besins Healthcare. “Drug of first choice” claims and similar claims must be supported by adequate and relevant clinical evidence. Unsupported comments about competitors or their products are not allowed.

- H. Comparative Claims handling. In addition to the requirements listed above, the following requirements relating to comparative claims must be respected:
1. Comparative claims are allowed when properly supported by data and in accordance to local regulations.
  2. The use of trade names of competing products is guided by local regulations.
  3. The comparative use of adverse drug reaction data in promotional material is recommended only as part of a comprehensive and fair comparison of drugs and if otherwise allowed.
  4. Comparative superiority claims are allowed only if they are based on data from adequate and well-controlled clinical trials, and if they are consistent with the body of other clinical data.
  5. Claims referring to differences in efficacy between drugs are permissible only if the difference is statistically significant and clinically relevant.
- I. Prohibition of use of certain words or materials without qualifications. In any promotional material these practices are prohibited:
1. Using the word “safe” without proper qualification;
  2. Using the word “effective” without proper qualification;
  3. Using the word “new” later than 1 year after the local launch (i.e. when the product or indication is not “new” anymore). This delay may be lengthened or shortened depending on the local requirements.
  4. Using the words “non toxic”, “no side effects”;
  5. Making unspecified and/or unreferenced claims about side effects and safety;
  6. Making absolute statements (i.e., the “only product”, etc) unless supported and referenced by scientific data.
  7. Using superlatives unless substantiated by scientifically sound and appropriately interpreted data.
  8. Using third party copyright-protected materials including logos, if not allowed by the local legislation or the owner of the materials.
- J. Updating Promotional Material. The promotional material must be reviewed on a regular basis (at the very least on a yearly basis) to ensure that it is still up to date and in accordance with the current prescribing information and/or when so required by applicable laws upon changes to the Promotional Materials. Where required by local legislation, the promotional materials must be cleared by the regulatory authorities.

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## 10. Events involving HCPs

Events organized by Besins Healthcare prioritize scientific or educational objectives and adherence to local regulations, ensuring appropriateness of venues and hospitality. Such events are under the responsibility of Medical Affairs.

### 10.1 Objectives of events organized by Besins Healthcare

The purpose and focus of all events, symposia, congresses and other promotional, scientific or professional meetings (“Events”) for HCPs organized or sponsored by Besins Healthcare should be to provide scientific or educational information and/or inform HCPs about products.


### 10.2 Location of events

Besins Healthcare’s Regions or Corporate Headquarters may not organize nor sponsor an Event for HCPs (including sponsoring HCP’s attendance to such an Event) that takes place outside of their home country unless it is appropriate and justified to do so from a logistical point of view or is justified by security concerns. Any such request must be approved in writing in advance by the Compliance Officer. However, international scientific congresses and symposia that derive participants from many countries are by their nature conducive to medical exchange and foster scientific education. They are therefore justified and permitted and do not require prior authorization from the Compliance Officer.

### 10.3 Promotional Information at events

Any promotional information appearing on exhibition stands or which is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- Host country regulations permit such an arrangement;
- The specifications of booths or promotional communication comply with the local regulations of the host country;
- The meeting is a truly international scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the event takes place;
- Promotional material (excluding promotional aids as defined in article) for a pharmaceutical product not registered in the country of the event should be accompanied by a suitable statement indicating the countries in which the product is registered, indicating that registration conditions differ internationally, and make clear that such product is not available locally;
- Promotional material that refers to the prescribing information (indications, warnings, etc) authorized in a country or countries in which the product is registered.

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#### 10.4 Appropriate venue

All events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Besins Healthcare must avoid using renowned or extravagant venues.

#### 10.5 Hospitality and entertainment

When Besins Healthcare organizes a meeting, refreshments and/or meals incidental to the main purpose of the event may be provided. Refreshments and/or meals may only be provided to participants of the Event and if they are moderate and reasonable as judged by local standards in accordance with regional policies.

No entertainment for HCPs may be provided or paid for by Besins Healthcare. Besins Healthcare will not pay or fund entertainment in any form. Any entertainment, even if secondary to the meal, is prohibited.

#### 10.6 Sponsorships

Besins Healthcare may sponsor HCP's attendance at Events provided such sponsorship is in accordance with the following requirements:


- The Event complies with the requirements in this Policy as described above;
- Sponsorship of the HCPs is limited to the payment of travel, meals, accommodation and registration fees;
- No payments are made to compensate HCP's for time spent in attending the Event;
- Any sponsorship to HCPs can never be conditional to an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.
- Any sponsorship must also comply with Besins' Anti-Corruption Policy GLAD-POL-005 and any other relevant policy.

#### 10.7 Guests of HCPs

Besins Healthcare shall not pay any cost associated with individuals accompanying invited HCP's. In any case, no entertainment, leisure or social activities shall be provided or paid for by Besins Healthcare for HCP's or their guests.

### **11. Use of HCPs as Consultants or Speakers**

Besins Healthcare may contract with HCPs to provide bona fide consulting services as is necessary and appropriate. Examples include, but are not limited to: speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at

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advisory board meetings, and participation in market research where such participation involves remuneration. Payment for these services shall be based on the fair market value, and all such engagements must be based on written agreements, genuine need, and maintain compliance with professional obligations and regulations.

### 11.1 Criteria for the HCP engagements

The following criteria are required for all HCP engagements:


- A written contract or agreement must be signed with Besins Healthcare prior to commencement of the services; this contract shall specify the nature of the services to be provided, and the basis for payment of the services.
- A legitimate need for the services must be clearly identified at Besins Healthcare and documented in advance. Upon request of the Compliance Officer, such documentation must be provided.
- The criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service.
- The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine;
- The hiring of the consultant must not run counter to his obligations under any professional organization to which he may belong which prohibits his being remunerated by Besins Healthcare;
- The compensation for the services must be reasonable and reflect the fair market value of the services provided;
- Where required, the employers, Medical Institutions or Regulatory Authorities must be notified of the intended HCP engagement and/or the remuneration provided.

## **12. Gifts and samples**

Samples may be provided to HCPs in accordance with applicable laws. When permitted, samples must only be given for the purpose of distribution to patients. The purpose of the samples is to allow the HCP and patients to become familiar with our products. Sale of samples is expressly prohibited. Samples must be used for patient care, properly labeled, and accounted for.

Payments in cash or cash equivalents, such as gift certificates, must not be provided or offered to HCP's. Gifts for the personal benefit of the HCP (such as sporting or entertainment tickets, electronic items, etc.) must not be provided or offered. Nothing may be offered or provided to a HCP with the intent of having an undue influence on the HCP's decision of prescribing, dispensing, recommending, purchasing, supplying or administering products.

In some countries, if allowed under local law and in accordance with local practice, an inexpensive customary gift unrelated to the practice of medicine may be given on an exceptional basis to a HCP

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in acknowledgment of significant national, cultural or religious events. However, even in such circumstances, these gifts may not be provided when they could be perceived as interfering with the independence of the HCP in prescribing, recommending or purchasing Pharmaceutical Products. These gifts must also comply with the limits and regulations prescribed in the Policy GLAD POL-005 (Anti-Corruption Policy) as well as the IFPMA code and local regulations. Where local laws and/or compliance guidelines prohibit any such kind of gifts, these are not acceptable under this Policy.

Promotional aids of minimal value and quantity may be provided or offered to HCP if relevant to the practice of the HCP. A promotional aid is a non-monetary item given for a promotional purpose. Possible examples include inexpensive pens and notepads. Promotional items intended for the personal benefit of the HCP, such as music CDs, paintings or food baskets are not acceptable. Where local laws and/or compliance guidelines prohibit any such kind of promotional aids, these are not acceptable under this Policy.

Promotional literature such as detail aids, leave-behind pieces, booklets, etc. are not considered to be promotional aids and do not fall under the scope of this policy.

### 13. Reporting protocol


Any violation of this policy must be promptly reported to line managers and/or the Compliance Officer. Whistleblower protection is guaranteed for all good faith reports as per the Whistleblower Protection Policy (GLAD-POL-007).

### 14. Review of this policy

This Policy shall be reviewed on a yearly basis by the Compliance Committee. An ad hoc review may be initiated earlier by the Compliance Officer and submitted to the Compliance Committee in case the application and enforcement of this Policy brings up organizational or structural issues within the functioning of the policy.

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Signed by:  
*Nicolas Besins*

 Signer Name: Nicolas Besins  
Signing Reason: I approve this document  
Signing Time: 25 July 2025 | 10:59:30 AM CEST  
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**Nicolas Besins**

CEO

Signed by:  
*Alexandre Besins*

 Signer Name: Alexandre Besins  
Signing Reason: I approve this document  
Signing Time: 24 July 2025 | 3:45:13 PM CEST  
27805063219341429B04B281A7ABE547

**Alexandre Besins**

CEO

FORM GLAD-F-002/01

**PROMOTIONAL MATERIAL APPROVAL FORM**

1.	Name	
2.	Role, Title	
3.	Department	
4.	Date sent:	
5.	Date received at Corporate Marketing Department:	
6.	Approval (Y/N)	
7.	If response is “N” to question 6, what are the motivations? Corrective action suggested?	
8.	Date received at Corporate Medical Department:	
9.	Approval (Y/N)	
10.	If response is “N” to question 9, what are the motivations? Corrective action suggested?	
11.	Date received at Corporate Regulatory Department:	
12.	Approval (Y/N)	
13.	If response is “N” to question 12, what are the motivations? Corrective action suggested?	
14.	Date received at GLAD:	
15.	Approval (Y/N-	
16.	If response is “N” to question 15, what are the motivations? Corrective action suggested?	
17.	Viewed by the Compliance Officer:	

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