

Supplier Letter of Attestation

The undersigned, on behalf of the supplier identified below attests to the following checked items (*check only one*)

- 1. The activity that my company engages in on behalf of a J&J Pharmaceutical Affiliate is considered a Covered Function and as a result certain employees are considered covered persons under the terms of the Johnson & Johnson CIA.
- 2. My company engages in a Covered Function on behalf of a J&J Pharmaceutical Affiliate, but not more than 160 hours.
- 3. The activity that my company engages in on behalf of a J&J Pharmaceutical Affiliate is not considered a Covered Function.

If box #1 is checked above, please complete the remaining sections below. If box #2 or #3 is checked above, please skip to and complete the required signatory section:

- Ineligibility screenings will be conducted for current qualified employees within 30 days of this signed attestation. New qualified employees will be screened prior to initiating work on a J&J Pharmaceutical Affiliate project. If deemed ineligible to participate in Federal healthcare programs or activities on behalf of a J&J Pharmaceutical Affiliate, employees will be removed from the J&J Pharmaceutical Affiliate assignment and will be replaced by a qualified individual who is eligible to participate in Federal healthcare programs.
- My company has a similar or more restrictive ineligibility screening process than required by the Johnson & Johnson CIA and all covered persons will be screened in accordance with it.
- Local laws prohibit ineligibility screening of individuals outside the U.S.

And:

- Current qualified employees will complete the J&J Pharmaceutical Affiliates Supplier Training within 30 days of this signed attestation. New qualified employees will complete training prior to initiating work on a J&J Pharmaceutical Affiliate project.
- Local laws prohibit training individuals outside their native languages.

And:

- All qualified employees will review the J&J Pharmaceutical Affiliates Code of Conduct as required and will certify electronically or in writing that he or she has received, read, understood, and will abide by the principles outlined within it when working on behalf of JJPA.

NOTE: All documentation to evidence the requirements above must be retained by the supplier and made available to J&J or JJPA in the event of an audit.

The undersigned is authorized by the entity to make this representation on behalf of the entity as evidenced by the signature below.

Name of Entity

Printed Name

Address

Signature

Date

Title

Email Address

Thank you for your prompt attention to this matter and your commitment to compliance. Please return this completed Attestation via email to cia@its.nj.com or fax to 908-253-3518. If you have any questions, please contact us at 609-730-2HCC (2422) or via e-mail at cia@its.nj.com

Appendix A. Instructions for Completing the Supplier Letter of Attestation

The Supplier Letter of Attestation may be completed and returned in one of the following ways:

1. Complete, sign, and return the letter
 - a. Via fax to 908-253-3518 or
 - b. Via email to cia@its.jnj.com or
 - c. Via postal mail to

Chris Matteson
Senior Director, CIA Operations
1125 Trenton-Harbourton Rd.
Titusville, NJ 08560

Completing the Supplier Letter of Attestation: These instructions will assist you in determining the appropriate box to select in the 1st section of the Supplier Letter of Attestation.

1. If one or more employees of your company engages in ***Covered Functions*** for a J&J Pharmaceutical Affiliate (JJPA) government reimbursed product (Appendix B) **for more than 160 hours** select the option below.

The activity that my company engages in on behalf of a J&J Pharmaceutical Affiliate is considered a Covered Function and as a result certain employees are considered covered persons under the terms of the Johnson & Johnson CIA.

- a. Complete each of the remaining sections of the letter regarding Ineligibility (Appendix C), Training (Appendix D), and Code of Conduct (Appendix E).
 - b. Sign and complete the required signatory information (name, title, email, etc.)
2. If employees of your company only engage in ***Covered Functions*** for a JJPA government reimbursed product for **less than 160 hours** select the option below.

My company will not engage in a Covered Function on behalf of a J&J Pharmaceutical Affiliate for more than 160 hours.

- a. Sign and complete the required signatory information (name, title, email, etc.). The remaining sections of the attestation are not required.
3. If there are no employees of your company who engage in ***Covered Functions*** for a JJPA government reimbursed product select the option below.

The activity that my company engages in on behalf of a J&J Pharmaceutical Affiliate is not considered a Covered Function.

- a. Sign and complete the required signatory information (name, title, email, etc.). The remaining sections of the attestation are not required.

Covered Functions

Promotional Functions includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to any applicable Promotional Review Committee (PRC) process and any applicable review committees for promotional materials.

- *Examples include but are not limited to:* Contract sales organization activities, public relations activities, call center activities, sales planning, speaker training, promotional speaker programs and distributors of sample products.

Product Related Functions includes: The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to HCPs and HCIs about Government Reimbursed Products, including those functions relating to any applicable medical review committee(s) and to medical affairs/medical services of any J&J Pharmaceutical Affiliate; (b) contracting with HCPs and HCIs licensed in the United States to conduct post-marketing clinical trials, post-marketing investigator-initiated studies (IISs), and all other types of post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to post-marketing clinical trials and other post-marketing studies for Government Reimbursed Products (including studies of investigational and other uses and indications outside the currently approved uses and conditions of use); and (d) activities related to the submission of information about Government Reimbursed Products to compendia (such as DrugDex or other compendia of information about Government Reimbursed Products).

- *Examples include but are not limited to:* Development of materials to HCPs and HCIs in response to Medical Information Requests, authorship, contracting with HCPs and HCIs licensed in the US to conduct post-marketing studies, authorships and publications related to post-marketing studies and compendia activity.

Managed Healthcare Related Functions refers to: Promotional Functions and Product Related Functions as they relate to interactions between J&J and/or J&J Pharmaceutical Affiliates and: (1) government payers, including the Federal government, state Medicaid programs, pharmacy benefits managers (PBMs), or other individuals or entities under contract with or acting on behalf of Medicaid, Medicare and other government Payers; and (2) institutional purchasers or providers, institutional pharmacies, long-term care or specialty pharmacies, or other individual or entities under contract with or acting on behalf of institutional purchasers or providers and who are in a position to influence the use of Government Reimbursed Products in the institution. Marketing, formulary, contracting, and rebate activities undertaken in connection with the sale of Government Reimbursed Products.

- *Examples include but are not limited to:* Interactions with the payers and purchasers above as it relates to marketing, formulary, contracting, and rebate activities undertaken in connection with the sale of Government Reimbursed Products.

Appendix B. J&J Pharmaceutical Affiliates U.S. Government Reimbursed Products

For the purposes of this process, the following list of products are to be used to evaluate the activities of employees, contractors, subcontractors or other persons who perform Covered Functions on behalf of J&J Pharmaceutical Affiliates.

<u>Janssen Pharmaceuticals, Inc.</u>	
ACIPHEX® ((rabeprazole sodium)	ORTHO MICRONOR® (norethindrone)
AXERT® (almotriptan malate)	ORTHO TRI-CYCLEN LO® (norgestimate/ethinyl estradiol)
CONCERTA® (methylphenidate HCl)	ORTHO TRI-CYCLEN® (norgestimate/ethinyl estradiol)
DITROPAN XL® (oxybutynin chloride)	ORTHO-CEPT® (desogestrel/ethinyl estradiol)
DORIBAX® (doripenem)	ORTHO-CYCLEN® (norgestimate/ethinyl estradiol)
DURAGESIC MATRIX® (fentanyl transdermal system)	ORTHO EVRA® (norelgestromin/ethinyl estradiol)
DURAGESIC® (fentanyl transdermal system)	ORTHO-NOVUM® (ethinyl estradiol/ norethindrone/)
ELMIRON® (pentosan polysulfate sodium)	PANCREAZE® (pancrelipase)
HALDOL DECANOATE® (haloperidol decanoate)	PARAFON FORTE DSC® (chlorzoxazone)
HALDOL® (haloperidol)	RAZADYNE ER® (galantamine HBr ER)
INVEGA SUSTENNA® (paliperidone palmitate)	RAZADYNE® (galantamine)
INVEGA® (paliperidone)	RISPERDAL CONSTA® (risperidone)
INVOKANA® (canagliflozin)	RISPERDAL M-TAB® (risperidone)
INVOKAMET® (canagliflozin/metformin hydrochloride)	RISPERDAL® (risperidone)
LEVAQUIN IV® (levofloxacin)	SPORANOX® (itraconazole)
LEVAQUIN® (levofloxacin)	TERAZOL® (terconazole)
MODICON® (norethindrone/ethinyl estradiol)	TOPAMAX® (topiramate)
NIZORAL® (ketoconazole topical)	ULTRACET® (tramadol HCL)
NUCYNTA® (tapentadol HCL)	ULTRAM ER® (tramadol HCL)
NUCYNTA IR® (tapentadol HCL)	ULTRAM® (tramadol HCl)
NUCYNTA ER® (tapentadol HCL)	XARELTO® (rivaroxaban)
<u>Janssen Biotech Inc.</u>	<u>Janssen Scios</u>
DOXIL® (doxorubicin HCl liposome injection)	NATRECOR® (nesiritide)
IMBRUVICA® (ibrutinib)	
PROCRIT® (epoetin alfa)	<u>Janssen Therapeutics</u>
REMICADE® (infliximab)	COMPLERA® (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)
SIMPONI® (golimumab)	ENDURANT® (rilpivirine)
SIMPONI ARIA® (golimumab)	INTELENCE® (etravirine)
STELARA® (ustekinumab)	OLYSIO® (simeprevir)
SYLVANT® (siltuximab)	PREZISTA® (darunavir)
ZYTIGA® (abiraterone acetate)	SIRTURO® (bedaquiline)

Appendix C. Employee Ineligibility Guidelines

Screening of employees for ineligibility is a process that must be completed on an annual basis. As long as persons continue to engage on behalf of a J&J Pharmaceutical Affiliate (JJPA) for more than 160 hours they will be considered covered by the Johnson & Johnson CIA (the CIA).

To complete the screening process, suppliers can employ the services of a third party organization that specializes in ineligibility screening, such as Yale Associates, or screen the individual persons themselves against the following databases:

- List of Excluded Individuals, Office of Inspector General (OIG) HHS at <http://exclusions.oig.hhs.gov/>
- General Services Administration (GSA), Excluded Parties List System (EPLS) at <https://www.sam.gov/portal/SAM/>
- Food & Drug Administration Debarment List (FDA) at <http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm>

In the event that an employee, contractor, subcontractor or other person engaged in 160 hours or more on behalf of a JJPA is found on any of the above websites or convicted of a criminal offense he or she must be removed from working on the JJPA's behalf. The supplier must maintain a log of the screening activities and actions taken against individuals found on the website should the JJPA require it in support of the CIA reporting obligations. The log must at a minimum include:

- Name
- Title
- Job Function/Responsibilities
- Screening Date
- Action Taken

It is important to note on the Supplier Letter of Attestation where local laws prevent ineligibility screening from taking place.

For your reference, the contact information for Yale Associates is:

Yale Associates
Tom Farley, President
631-732-4400

NOTE: All documentation to evidence that the ineligibility screening was completed must be retained by the supplier and made available to J&J or JJPA in the event of an audit.

Appendix D: Training Guidelines and Materials

The Johnson & Johnson CIA Corporate Integrity Agreement (the CIA) requires all employees, contractors, subcontractors, or other persons working for more than 160 hours on Covered Functions on behalf of a J&J Pharmaceutical Affiliate (JJPA) Government Reimbursed Product understand and comply with all applicable laws and regulations governing the sale and marketing of healthcare products in the United States, the laws and regulations governing U.S. government reimbursed products and the CIA and complete job-specific training on the JJPA policies and procedures, the JJPA Code of Conduct and the CIA.

To meet these requirements, the JJPA have developed a comprehensive training program. If your organization currently has its own comprehensive health care compliance training in place, please note this on the Supplier Letter of Attestation.

Accessing the Training:

- Please [click here](#) to access the **HCC&P Third-Party Training**
- Enter your complete and accurate information into the Articulate Online login page, then click “Continue.”
- The course will automatically launch. Should you need to exit you will be bookmarked and able to resume training later.
- **Upon reviewing the training in its entirety, you will be marked in the system as complete. There is no completion certificate provided.**

Ensure your computer speakers are enabled and the volume is set at a comfortable level to follow and comprehend the training. In some cases, external systems could be set to block pop-up windows.

Appendix E. J&J Pharmaceutical Affiliates Health Care Compliance Code of Conduct

The J&J Pharmaceutical Affiliates (JJPA) Health Care Compliance Code of Conduct can be accessed by clicking the link below and going to the Our Company page and selecting Compliance Principles.

- <http://www.omjpi.com./shared/company/janssen-biotech/Janssen-HCC-Code-of-Conduct.pdf>

The Code of Conduct has been designed to ensure that all employees and third party suppliers covered persons can use it as both a learning tool and a reference guide. All covered persons identified by the Supplier as qualifying under the terms of the Johnson & Johnson CIA must certify electronically or in writing that he or she has received, read, understood, and will abide by the principles outlined in the JJPA Code of Conduct.

Hard copies of the JJPA Code of Conduct are available upon request by e-mailing Health Care Compliance at cia@its.jnj.com, or by calling 1-609-730-2HCC (2422).

NOTE: All documentation to evidence that the Code of Conduct certification is complete must be retained by the supplier and made available to J&J or JJPA in the event of an audit.