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**National Association of Boards of Pharmacy® (NABP®) 1600 Feehanville Drive**

**Mount Prospect, Illinois 60056**

**Website:** [***www.nabp.pharmacy/programs/medical-device-distributor***](http://www.nabp.pharmacy/programs/medical-device-distributor)

**Email:** [**vdip@nabp.pharmacy**](mailto:vdip@nabp.pharmacy)

**Phone: 847/391-4539**

**OTC Medical Device Distributor Accreditation**POLICY AND PROCEDURE ASSESSMENT

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| **APPLICANT INFORMATION** | | | | | | | | |
| **Applicant’s Legal Business Name** | | | **Doing Business As (DBA) Name – If applicable** | | | | | **Date** |
|  | | |  | | | | |  |
| **Applicant’s Physical Address of Facility** | | **Any other businesses handling OTC Medical Devices at this facility?** | **Contact Person for Accreditation** | | | | | |
|  | | **Yes  No** | **Name** | | | **Telephone Number** | | **Email Address** |
|  | | |  | |  |
| **Type of Application** | | | **Does your facility take possession of the OTC Medical Devices that you own?** | | | **Is the facility’s OTC Medical Device storage area air conditioned?** | | |
| **New Applicant  Reaccreditation  Other** | | | **Yes  No** | | | **Yes  No  N/A** | | |
| **Type of Facility: (Check All That Apply)** | | | | | | | | |
| **WD - Wholesale Distributor** | **3PL - Third Party Logistics Provider** | | | **RD - Reverse Distributor (non-saleable return products only) \*If handling saleable return products, contact NABP** | | | | |
| **MFR - Manufacturer** | **503B - Outsourcing Facility** | | | **SD - Sample Distributor** | **RPKG - Repackager** | | **VD - Virtual Distributor** | |
| **AD – API Distributor** | **DD – Rx Device Distributor** | | | **VET - Veterinary Prescription Drugs** | **OTC Medical Devices** | | **Other (Describe)** | |
| **GENERAL COMMENTS** | | | | | | | | |
| **Reviewer Comments:** | | | | | | | | |
| **Applicant Comments:** | | | | | | | | |
| **INSTRUCTIONS** | | | | | | | | |
| **IMPORTANT NOTE: Save this document to your computer using Microsoft Word. Complete it electronically and submit the final Word version of the document and referenced policies and procedures (P&Ps) back to** [**VDIP@nabp.pharmacy**](mailto:VDIP@nabp.pharmacy)**. Handwritten assessments are not acceptable. PDF assessments are not acceptable.**  Familiarize yourself with this *Policy & Procedure Assessment* prior to completion. Contact [VDIP@nabp.pharmacy](mailto:VDIP@nabp.pharmacy) or 847/391-4539 with any questions.  **Instructions to ALL Applicants**   1. P&P List: Using the “P&P Index” located at the back of this document, create a list of all shared P&Ps indicating which locations use the P&P. 2. Functional List: Using the “Off-Site Functions List” template located at back of this document, create a list of all functions performed off site that are essential to your business and relative to the purpose of brokering, shipping, and receiving OTC Medical devices. 3. Does Not Apply To: Focus points not applying to specific facility types are referenced in this column. Refer to the “Facility Type” listing above in “Applicant Information” for facility type abbreviations. 4. P&P Type: Indicate whether the P&P referenced is a “Shared” or a “Site-Specific” document. 5. P&P Name or Number: For all applicable “Focus Points,” insert the P&P name or number that corresponds to the electronic file containing the P&P. 6. P&P Page Number: Provide the page number within your P&P where the specific criterion can be found. 7. N/A: If a criterion does not apply to your business operation, type “N/A” in the P&P Name or Number column and then explain in the “Applicant Comments” section.   **ADDITIONAL Instructions to Those That DO NOT TAKE POSSESSION OF PRODUCT (“Virtual Distributors”)**   1. P&P Name or Number: For functions performed by your third-party logistics provider (3PL) or business partner, include in the place of the “P&P Name or Number” *the DBA name or number, as indicated on your Functional List, located on the final page of this document*. | | | | | | | | |

| **EXAMPLE** | | | | | | |
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| **FOCUS POINT** |  | **P&P Type** | **P&P Name or Number** | **P&P Page Number** | **X?** | **Date of Compliance** |
| **Quarantine, Disposition, Returns, and Disposal**  May be included in P&Ps for product returns and destructions |  |  |  |  |  |  |
| Process for determining product to be in quarantine |  | Shared | **SOP.QT.002.V4 – Product Quarantine** | **5** |  |  |
| Process for ensuring the safety, identity, strength, quality, and purity of prescription products to be returned to vendors, active stock, destroyed, or held for Food and Drug Administration (FDA) |  | Site-Specific | **SOP.QT.001.V2 – Returned Product Integrity Assessment** | **3-4** |  |  |
| Process for creating documentation showing that proper conditions were maintained and that these documents were provided to the manufacturer or device distributor to which products are returned |  | Site-Specific | **SOP.QT.011.V6 – Shipping Product Returns** | **8** |  |  |

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| **APPLICANT’S POLICY & PROCEDURE INFORMATION** |

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| **FOCUS POINT** |  | **P&P Type** | **P&P Name or Number** | **P&P Page Number** | **X?** | **Date of Compliance** |
| **Licensing and Compliance with Laws/Regulations** |  |  |  |  |  |  |
| Process for determining requirement for licensure in a state |  | Choose an item. |  |  |  |  |
| Process for obtaining and maintaining current licenses (if applicable) in all relevant jurisdictions |  | Choose an item. |  |  |  |  |
| Process for ensuring compliance with federal, state, and local laws/regulations in the host state and each state to which OTC Medical devices are shipped as required |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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| **FOCUS POINT** |  | **P&P Type** | **P&P Name or Number** | **P&P Page Number** | **X?** | **Date of Compliance** |
| **Operations** |  |  |  |  |  |  |
| Pre-employment process for ensuring all personnel who have access to the operation and handling of OTC Medical devices, or directly supervise those who do, meet the following qualifications prior to their association, employment, or contract: |  | Choose an item. |  |  |  |  |
| * Local and national criminal background checks |  | Choose an item. |  |  |  |  |
| * Initial toxicology screening |  | Choose an item. |  |  |  |  |
| * Appropriate education, experience, and minimum qualifications for the specific duties of the position |  | Choose an item. |  |  |  |  |
| Process for ensuring the title, duties, and qualifications of responsible persons and persons in charge, including facility managers or designated representatives, are documented and updated as needed |  | Choose an item. |  |  |  |  |
| Ongoing process for ensuring all personnel who have access to the operation and handling of OTC Medical devices, or directly supervise those who do, undergo the following regularly (as defined) after employment: |  | Choose an item. |  |  |  |  |
| * For-cause local and national criminal background checks |  | Choose an item. |  |  |  |  |
| * For-cause toxicology screening |  | Choose an item. |  |  |  |  |
| * Documented training of all personnel necessary to remain current on changes |  | Choose an item. |  |  |  |  |
| Process describing how the facility manager or designated representative duties are covered in their absence |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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| **Security**  May be addressed in separate P&Ps |  |  |  |  |  |  |
| Process describing the facility’s security alarm system |  | Choose an item. |  |  |  |  |
| * Alarms process for handling alarm activation during off hours |  | Choose an item. |  |  |  |  |
| * Description of how access is controlled |  | Choose an item. |  |  |  |  |
| Process for ensuring visitors are escorted at all times (this should also apply to housekeeping and pest control vendors) *(Recommended for Virtuals)* |  | Choose an item. |  |  |  |  |
| Process for ensuring only task-critical employees are allowed in the OTC Medical device storage and processing area |  | Choose an item. |  |  |  |  |
| Process for ensuring restrictions against food/drink, purses, coats, etc, in OTC medical device storage and processing areas are enforced |  | Choose an item. |  |  |  |  |
| Process for monitoring trash to prevent diversion of OTC Medical devices (prevention of OTC Medical devices being hidden in refuse and retrieved afterward) |  | Choose an item. |  |  |  |  |
| Information technology (IT) security process that covers the key elements of IT security, including secure login, off-site backup, firewalls, timeouts, and password security |  | Choose an item. |  |  |  |  |
| Process for separating and securing all aspects of the device distributor’s operation when the device distributor’s facilities are co-located with another business authorized to purchase OTC Medical devices |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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| **Vendor and Customer Validation** |  |  |  |  |  |  |
| Regular validation of the identity of each entity seeking to engage in the sale/distribution of OTC Medical devices with the applicant. This includes all sources from which OTC medical devices are purchased or received and all entities to which OTC medical devices are sold or shipped. |  | Choose an item. |  |  |  |  |
| * Initial and ongoing license validations of all entities (vendors and customers) engaged in the distribution of OTC Medical devices with the applicant conducted directly with federal and state regulatory agencies with jurisdiction over such entity (all licenses must be in good standing) |  | Choose an item. |  |  |  |  |
| Criteria for denying business with any entity, including all vendors (sources) and customers (recipients) seeking to engage in the distribution of OTC medical devices with the applicant |  | Choose an item. |  |  |  |  |
| Process for establishing the legitimacy of OTC Medical devices purchased or received from device distributor sources which purchase such OTC Medical devices exclusively from the manufacturer |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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| **FOCUS POINT** | **Does Not Apply To** | **P&P Type** | **P&P Name or Number** | **P&P Page Number** | **X?** | **Date of Compliance** |
| **Inbound OTC Medical Devices and Receiving Processes** |  |  |  |  |  |  |
| Processes for examining inbound OTC Medical devices to ensure containers and labeling are not suspected of being damaged, adulterated, misbranded, counterfeited, diverted, tampered with, or are otherwise unlawful or unfit for distribution |  | Choose an item. |  |  |  |  |
| * Ensure OTC Medical devices whose sealed outer and/or secondary containers have been opened/used are identified, quarantined, and properly disposed of. |  | Choose an item. |  |  |  |  |
| * Verify that OTC Medical devices match shipping receipts (OTC Medcial device/shipper validation). |  | Choose an item. |  |  |  |  |
| * Include visual inspections of OTC Medical devices |  | Choose an item. |  |  |  |  |
| * Include plan of action for when suspect product is identified, including quarantining product.***See suspect product section below for additional handling requirements.*** |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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| **Legitimate Medical Device Determination**  **-**  The term *Legitimate Medical Device* means a product for which there is no reason to believe that such product:   1. is potentially counterfeit, diverted, or stolen; 2. is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; 3. is potentially the subject of a fraudulent transaction; or 4. appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. |  | Choose an item. |  |  |  |  |
| Processes to assist in the timely identification of legitimate medial devices -, which: |  | Choose an item. |  |  |  |  |
| * ensure such measures incorporate regular vigilance and awareness to identify suspicious activity or potential supply chain threats; and |  | Choose an item. |  |  |  |  |
| * Includes a process for making timely legitimate medical device determinations |  | Choose an item. |  |  |  |  |
| Upon making a determination that a medical device in the possession or control of the applicant is not a legitimate medical device, processes for: |  | Choose an item. |  |  |  |  |
| * quarantining the medical device within the possession or control of the applicant from medical devices intended for distribution until such medical device is cleared or dispositioned; |  | Choose an item. |  |  |  |  |
| * promptly conducting an investigation in coordination with manufacturers, vendors and customers, as applicable, to determine whether the medical device is an legitimate |  | Choose an item. |  |  |  |  |
| * maintaining the records of a suspect product investigation for no less than three years after the conclusion of the investigation. |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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| **Temperature Standards** |  |  |  |  |  |  |
| Process for ensuring OTC Medical devices are stored at temperature standards according to the device labeling or United States Pharmacopeia (USP) standards. The most common temperature labeling requirements, although not all inclusive, are: |  | Choose an item. |  |  |  |  |
| * + Controlled Cold Temperature (CCT) 36° to 46° F |  | Choose an item. |  |  |  |  |
| * + Controlled Room Temperature (CRT) 68° to 77°F     - Excursions allowed from 59° to 86°F, provided the mean kinetic temperature does not exceed 77°F |  | Choose an item. |  |  |  |  |
| * Process to maintain an electromechanical or electronic recording and monitoring system that operates continuously (24/7/365) in all device storage areas. The system must provide recorded data (recording) as well as the real-time alarm status of excursions (monitoring) on a continuous (24/7/365) basis |  | Choose an item. |  |  |  |  |
| * Temperature monitoring equipment calibration frequency should be at least annually |  | Choose an item. |  |  |  |  |
| * 24/7/365 plan of action when temperature or humidity excursions occur, including device assessment |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **Humidity Standards**  **(if applicable)** |  |  |  |  |  |  |
| Processes for monitoring humidity to ensure all OTC Medical devices are stored according to the product labeling |  | Choose an item. |  |  |  |  |
| * Monitoring and recording all areas 24/7/365 |  | Choose an item. |  |  |  |  |
| * Humidity monitoring equipment calibration frequencies |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **Inventory Controls** |  |  |  |  |  |  |
| Process for identifying unusual OTC Medical device orders, including unusual ordering patterns and amounts, and payment that identify potential diversion or criminal activity. |  | Choose an item. |  |  |  |  |
| Process for identifying, recording, and reporting losses, thefts, or otherwise missing OTC Medical devices |  | Choose an item. |  |  |  |  |
| * Inventory/cycle count schedule |  | Choose an item. |  |  |  |  |
| * Correcting all errors, inaccuracies, or other adjustments in OTC Medical device inventories |  | Choose an item. |  |  |  |  |
| * Inventory adjustments with approval by authorized personnel |  | Choose an item. |  |  |  |  |
| * Protection against unauthorized access to computers or electronic records for purposes of concealing theft or diversion activities |  | Choose an item. |  |  |  |  |
| * Conducting internal investigations of inventory discrepancies to detect losses/thefts and other possible criminal activity |  | Choose an item. |  |  |  |  |
| * In-transit losses/thefts investigated with carrier and trended for evaluation of carrier’s continued service |  | Choose an item. |  |  |  |  |
| Process for import and/or export when applicable |  | Choose an item. |  |  |  |  |
| * Import process must include FDA and U.S. Customs clearance |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **FOCUS POINT** | **Does Not Apply To** | **P&P Type** | **P&P Name or Number** | **P&P Page Number** | **X?** | **Date of Compliance** |
| **Shipping / Outbound** |  |  |  |  |  |  |
| Process for ensuring the oldest approved stock or short-dated OTC Medical devices are distributed first |  | Choose an item. |  |  |  |  |
| Process for ensuring the identity of the OTC medical devices in each outgoing shipment and that the device has not been damaged or held under improper conditions while at the applicant’s facility (prior to shipping) |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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| **Recalls** |  |  |  |  |  |  |
| Process for handling recalls and voluntary and written withdrawals of OTC Medical devices |  | Choose an item. |  |  |  |  |
| * OTC Medical device is removed from active inventory and quarantined |  | Choose an item. |  |  |  |  |
| * Handling returned OTC Medical devices including screening returns against a list of recent recalled devices |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
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| **Quarantine, Disposition, Returns, and Disposal**  May be included in P&Ps for OTC medical device returns and destructions |  |  |  |  |  |  |
| Process for determining and documenting OTC medical devices to be quarantined (due to temperature excursions or quality hold, damaged, outdated/short-dated, otherwise unfit for distribution, etc) |  | Choose an item. |  |  |  |  |
| Process for determining and documenting devices to be quarantined (recalled medical devices and suspect product/illegitimate product) |  | Choose an item. |  |  |  |  |
| Documented disposition of quarantined OTC Medical devices with rationale for returning it to active stock, disposal, return to manufacturer/distributor, etc |  | Choose an item. |  |  |  |  |
| * Process for identifying and handling outdated OTC Medical must be segregated from other OTC Medical devices (quarantined) |  | Choose an item. |  |  |  |  |
| **OTC Medical Device Destruction Process** |  | Choose an item. |  |  |  |  |
| * Documentation of returning to active stock or disposal |  | Choose an item. |  |  |  |  |
| * Any on-site disposal must be witnessed and documented by a responsible member of the facility personnel |  | Choose an item. |  |  |  |  |
| * Certificate of destruction must be received from the destruction vendor/reverse distributor, if used and compared against product sent for destruction to ensure full inventory accountability. |  | Choose an item. |  |  |  |  |
| Process for disposing of containers, labels, and packaging that contain device information (Note: In some cases, packaging and labeling is disposed of with the device. If so, explain in the Applicant Comments section below and the following bullets do not apply.) |  | Choose an item. |  |  |  |  |
| * Process for destroying/defacing device cartons, overwraps, package inserts, and packaging waste generated as part of regular operations to prevent its retrieval and use for counterfeiting or diversion |  | Choose an item. |  |  |  |  |
| * Certificate of destruction received from destruction vendor/reverse distributor, if used |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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| **Records**  Compliance may be met through an all-inclusive document or in the individual operational documents. |  |  |  |  |  |  |
| A process to establish and maintain records related to the receipt, storage, wholesale distribution, and disposition (including any investigations) of all OTC Medical devices, including but not limited to, invoices, packing slips, shipping records, sales invoices, agreements, leases, deeds, and certificates of destruction. |  | Choose an item. |  |  |  |  |
| * Process for identification, storage, access, and protection of such records |  | Choose an item. |  |  |  |  |
| * Process for making all records accessible for inspection within two business days of a request by an authorized official of a federal, state, or local law enforcement agency |  | Choose an item. |  |  |  |  |
| * Process for maintaining all records for a minimum of three years-. |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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| **Crisis Operations** |  |  |  |  |  |  |
| Process for operations during a disaster that affects the facility’s security or operation, including: |  | Choose an item. |  |  |  |  |
| * After-action assessment of OTC Medical devices to ensure their continued integrity |  | Choose an item. |  |  |  |  |
| * Record preservation |  | Choose an item. |  |  |  |  |
| * Backup/outsourced resources (power, security, etc.) |  | Choose an item. |  |  |  |  |
| * Reporting to NABP, - and the state licensing agency when the facility is rendered inoperable for 10 or more days. |  | Choose an item. |  |  |  |  |
| **Reviewer Comments:** | | | | | | |
| **Applicant Comments:** | | | | | | |

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For facilities that share policies and procedures (P&Ps), list all P&Ps. Place an “X” in the appropriate column to indicate which facility(ies) uses the P&P.

**National Association of Boards of Pharmacy® (NABP®) 1600 Feehanville Drive**

**Mount Prospect, Illinois 60056**

**Website:** [***www.nabp.pharmacy/programs/medical-device-distributor***](http://www.nabp.pharmacy/programs/medical-device-distributor)

**Email:** [**vdip@nabp.pharmacy**](mailto:vdip@nabp.pharmacy)

**Phone: 847/391-4539**

**OTC Medical Device Distributor Accreditation**POLICY & PROCEDURE ASSESSMENT

**P&P Index**

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|  | | | Enter the applicable facility location in the column header. If additional columns are needed type over  the “example” facility names. | | | | | |
| **P&P Name** | **P&P Number** | **File Name of Document**  **Sent to NABP** | **[Example] ABC pharmaceutical Nashville, TN** | **[Example] ABC pharmaceutical Chicago, IL** | **[Example] ABC Pharma**  **dba 123 Distr**  **New York, Ny** | **[facility name]** | **[facility name]** | **[facility name]** |
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| **[Example]** Receiving | SOP 123 | SOP123.doc | X |  | X |  |  |  |
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**OTC Medical Device Distributor Accreditation**POLICY & PROCEDURE ASSESSMENT

**Off-site functions List**

**National Association of Boards of Pharmacy® (NABP®) 1600 Feehanville Drive**

**Mount Prospect, Illinois 60056**

**Website:** [***http://www.nabp.pharmacy/programs/vawd***](http://www.nabp.pharmacy/programs/vawd)

**Email:** [**vdip@nabp.**](mailto:VDIP@nabp.pharmacy)**pharmacy**

**Phone: 847/391-4539**

Provide the requested information for *all* functions performed off site that are essential to your business and relative to the purpose of brokering, shipping, and receiving prescription OTC Medical devices.

List: Third-Party Logistics Providers (3PLs), “Other” Business Partners, and Intra-Company Contributors

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|  | **Function Performed** | **Relationship Type** | **Legal Business Name (LBN)** | **Doing Business As Name (DBA)** | **Complete Address** |
| 1 | [Example] Stock, Pick, and Ship | 3PL | Zeta Pharmaceutical Shipping, Inc | Zeta Ships | 555 Abraham Way  Island Lake, WI 66652 |
| 2 | [Example] License Verification | "Other" Bus Partner | Anika Data Services | Anika Data Services | 538 Lakeland Ave  San Antonio, MI 58399 |
| 3 | [Example] State Licensing | Corporate Parent | Alpha Company, LLC | Alpha Company, LLC | 3535 Score Rd  Fish Creek, TX 85622 |
| 4 | [Example] Stock | Same Co/Other Location | Alpha Company, LLC | Alpha Company, LLC | 962 Washington Creek  Park Place, NY 68568 |
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