PROCEDURE: WI-100038 [A]

Title: Interim Advertising and Promotional (Ad/Promo) Review and Approval Procedure

Nondisclosure Statement

1. Contents

2. Purpose

2.1. Bioventus is committed to promoting its products and services in compliance with applicable laws and regulations and applicable Bioventus policies. The purpose of this procedure is to outline the requirements for the creation and dissemination of product advertising, promotional materials and other communications as specified herein for Bioventus and its subsidiaries and provide clear expectations for various roles involved in preparing and/or reviewing content to be approved.

3. Scope

3.1. This document applies to all Bioventus product advertising and promotional materials, including but not limited to communications intended for internal and external training, trade shows, brochures, sales sheets, video, and website content.

4. Applicable Documents

4.1. Applicable Documents

Document Number	Title
WIN-000226	Revising and Expiring a Document Using a Change Order in SmartSolve
POL-000090	External Standards List
CMPP-106-v1	Social Media Policy on Bionet

4.2. Reference Documents

4.2.1. A comprehensive list of applicable external standards and regulations can be found in POL-000090.

Source	Title
21 CFR 800	USA FDA applicable code of federal regulations
21 CFR 1	Subpart B – General Labeling Requirements
21 CFR 1271.3(c), 1271.3(d), 1271.3(f)	Homologous Use, HCT/P, and Minimal Manipulation Definitions – Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products
21 CFR 1271.10	361 HCT/P Criteria – Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products
21 CFR 1271.55, 1271.290, 1271.370	Records, tracking, and labeling – Regulatory Requirements of Human Cells, Tissues, and Cellular and Tissue-Based Products
97/55/EC	EU Directive Concerning Misleading Advertising (re: comparative advertising)
FD&C Act	USA Food Drug and Cosmetic Act (with amendments)
Submissions	Bioventus LLC Regulatory Submissions for Applicable Devices
FDA Guidance	2004 FDA Draft Guidance, Consumer-Directed Broadcast Advertising of Restricted Devices
European	Medical Device Directive MDD 93/42/EEC (Enforced January 1, 1995)
European	Directive 2007/47/EC (Enforced March 21, 2010)
European	Medical Device Regulation (MDR) 2017/745 (Enforced May 2020)
Canadian	Medical Device Regulation (May 7, 1998)
FDA Guidance	Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, December 2011
FDA Guidance	Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approval or Cleared Medical Devices, January 2009
FDA Guidance	Presenting Risk Information in Prescription Drug and Medical Device Promotion, May 2009

Source	Title
FDA Guidance	Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use
FDA Guidance	Internet / Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices
FDA Guidance	Medical Product Communications That Are Consistent with the FDA-Required Labeling
FDA Guidance	Scientific Information on Unapproved Uses of Approved/Cleared Medical Products
15 U.S.C. §§ 41 – 58	Federal Trade Commission Act

5. Responsibilities

Responsibility	Task
Document Owner	• The document owner is accountable for ensuring that all newly created and revised materials adhere to the applicable advertising and promotional (Ad/Promo) guidance as defined in this document. Responsibilities for initiation of a new piece or revision to existing piece: • Quality check of content and assigning appropriate approvers based on type of material or changes, and product portfolio. • The inclusion of the copyright symbol, part number and any trademarks used should be made clearly visible on the material (e.g., © Bioventus LLC All rights reserved. SMK-XXXXXX Rev. XX). • Maintain all supporting documentation on file [electronically in an agreed secure location i.e. Document Management System (DMS)] for reference purposes alongside the latest revision. • Review the digital file against the printed material, prior to dissemination (a specification should be available for all printed materials). • Ensure all material that requires translation will follow the designated process in Section 10.4.2 for translation (ensuring certificate of translation is received before publishing the material). The translated document must be linked to the English language master in SmartSolve for file referencing. • Communicates the changes to all relevant personnel through Cross-Functional Meetings. Include information on the indication, fair balance statements, summary etc., as applicable to the piece and ensure the font size is legible and proportionate to the overall size of the piece. • Captures action items and implementing verbal changes requested during meetings. • Track any revisions to existing material (electronically where possible) against the original document.
Ad/Promo Coordinator	• Enforces the responsibilities outlined by the Ad/Promo procedure. • Manages Ad/Promo Status Meeting. • Captures action items, decisions, and any other notes related to the Ad/Promo Status Meeting to be distributed via email. • Coordinates logistical and administrative elements of the process.
Cross-Functional Team	• Conducts a detailed pre-review of content, ensuring alignment, accuracy and compliance within their functional areas, and resolving any issues/discrepancies prior to submission for final review and approval. • At a minimum the team is comprised of a representative from Marketing, Clinical, Legal, and Regulatory. • As determined and deemed appropriate, additional team members may include a representative from Compliance, Medical Education, Sales, Sales Education, R&D, Creative Services, or Quality.

Responsibility	Task
Regulatory	• Review and approve all materials for compliance with applicable laws and regulations, including the Food, Drug and Cosmetic Act. • Review and assess the overall net impression for the material; ensuring technical, scientific and clinical content are appropriately used and referenced; and explicit labeling requirements. • Verify appropriate promotion of only approved or cleared uses of marketed devices and disclaimer statements and compliance with the cleared/approved uses. • Verify data supports comparative promotion and any claims of superiority. • The assigned Regulatory Representative will be available to meet with Document Owners and attend any cross-functional meetings in advance of any Ad/Promo submissions to help facilitate feedback and collaboration.
Marketing	• Facilitate stakeholder alignment to ensure a complete review process is executed prior to moving to the final approval stage. • Manage meetings with Cross-Functional Teams for cross-functional collaboration to gain stakeholder alignment, review and resolve issues prior to final approval of material. • Monitor supply of materials to the field. Updated pieces do not necessarily need to replace existing pieces until supply is exhausted (unless they need to be removed for legal reasons). Should any disseminated content need to be removed or replaced, a marketing representative will initiate the process for removal or replacement.
Marketing Lead	• Manage respective product portfolio materials. • Harmonize respective global materials, where appropriate.
Clinical	• Review and approve advertising and promotional materials for cleared/approved clinical use, and verifying clinical content is appropriately used and referenced. • Attend any applicable Cross-Functional Team meetings and/or meeting with Document Owners in advance of any Ad/Promo submissions to help facilitate the feedback and collaboration process.
Compliance	• Review and approve advertising and promotional materials consistent with Company policy and applicable industry codes of conduct. • Attend any Applicable Cross-Functional Team Meetings and/or Meeting with Document Owners in advance of any Ad/Promo submissions to help facilitate the feedback and collaboration process.

Responsibility	Task
Legal	• Review and approve advertising and promotional materials to ensure compliance with applicable laws, regulations and standards including intellectual property and trademark standards, anti-competitive issues, product liability issues, and other legal requirements. • Attend any applicable Cross-Functional Team meetings and/or meeting with Document Owners in advance of any Ad/Promo submissions to help facilitate the feedback and collaboration process.
Medical Education	• Prepare and edit material intended for use to educate healthcare professionals. • Ensure stakeholder alignment to support a complete review process prior to moving to the final approval stage. • Attend any applicable Cross-Functional Team meetings.
Sales Education	• Prepare and edit material intended for use to train employees and distributors about our products and indications. • Ensure stakeholder alignment to support a complete review process prior to moving to the final approval stage. • Attend any applicable Cross-Functional Team meetings.
Market Access	• Prepare and edit reimbursement-related material. • Ensure stakeholder alignment to support a complete review process prior to moving to the final approval stage. • Attend any applicable Cross-Functional Team meetings.
Creative Services	• Review and approve advertising and promotional • Create consistent corporate and product branding to ensure all branded print and digital assets adhere to corporate and product brand standards. Ensure trademarks correctly displayed. • Attend any applicable Cross-Functional Team meetings.
Configuration Analyst	• Initiate and close all documents in SmartSolve.

6. Definitions

6.1. Definitions specific to this document are shown in the following table:

Term	Definition
Comparative Claims	Statements (both text and graphics) that imply (directly or indirectly) that a Bioventus product is equal to, safer than, more effective than, or otherwise better than another product. Comparative claims include comparisons of Bioventus products to competitive products, as well as claims that compare one Bioventus product to another Bioventus product.

Term	Definition
Device Claims	Statements (both text and graphics) of safety, effectiveness, performance, or benefit of use (e.g., impact on quality of life) that are made in advertising or promotional materials. Claims can be conveyed through words, pictures, sound or unique positioning. Both direct claims and indirect claims (implied) are included. Direct claims are stated while indirect claims incorporate the 'intent' of the promotion (e.g., an adult only indication promoted with photographs of children for an implied pediatric indication, or an orthopedic indicated device promoted to neurosurgeons for an implied neurosurgical indication).
Labeling	For the purposes of this work instruction, labeling refers to any advertising or promotional materials. For finished device labeling refer to the Bioventus Medical Device Labeling Procedure SOP-0144 which includes Instructions for Use.
Restricted Device Brief Statement/ Brief Summary	A "restricted device" is a device that can only be sold, distributed or used upon the order of an authorized healthcare provider, generally referred to as prescription (Rx) devices. A device is misbranded if its labeling does not contain certain required information, such as a brief statement or brief summary of the intended uses and warnings, precautions, side effects and contraindications, as well as any special conditions put on the device by the FDA.
Instructions for Use (IFU)	The Bioventus document which provides the regulatory bodies' approved/cleared device's indications, contraindications, warnings, precautions, potential adverse events, and specific directions for use of the device.
Minimum Disclosure (Brief Summary)	The minimum wording within, or on, an advertising or promotional piece that complies with the FDA disclosure requirements. The required "Minimum Disclosure" is dependent on the FDA Classification of the device and whether any device or therapy claims or instructions for use are made in the piece.
On-label / Off-label Use	Off-label use means any use of a product that is not included in the approved or cleared 'indications for use' in the device labeling
Pending 510(k)	A 510(k) submitted to FDA, under review, clearance not yet achieved.
Prescription Use Device	A device for which the sale, distribution, and use are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug and Cosmetic Act under the authority of section 515(d)(1)(B)(ii). 21 CFR 810.109 (a)(2)(b): The label of the device bears the statement "Caution: Federal law restricts this device to sale by or on the order of a physician," or alternatively uses the symbol "Rx Only."

<table>
<tr>
<td>Materials</td>
<td>
For purposes of this procedure, Materials refers to any communication, in any format or medium, initiated, sponsored, or approved by the Company, that is intended to, or can reasonably be expected to, directly or indirectly promote, prescribe, recommend, purchase, supply, use, or support the use of a Company product or service. In addition, oral statements made by Bioventus representatives can also be considered promotional. Materials include, but are not limited to, all print and electronic media, such as:
<table>
<tr><td>Animations</td><td>Newspaper Articles</td></tr>
<tr><td>Audio/Visual recordings and videos</td><td>Patient Brochures</td></tr>
<tr><td>Branded Promotional products / giveaways that are not the product itself</td><td>Patient Incentives</td></tr>
<tr><td>Brochures</td><td>Patient stories and testimonials</td></tr>
<tr><td>Catalogues</td><td>Reference Texts</td></tr>
<tr><td>Branded or Product Specific Clinical Trial Recruitment Aids</td><td>Sales & Marketing Aids</td></tr>
<tr><td>Displays</td><td>Sales & Marketing Programs</td></tr>
<tr><td>Email Blasts to Sales Representatives that are promotional in nature or draw reference to a competitor’s product (internal and external)</td><td>Sales Education materials</td></tr>
<tr><td>Exhibition/Booth Displays Booth Set up, Banners, Product Placement</td><td>Product pages on social media outlets/blogs (e.g. LinkedIn, Facebook, Twitter, YouTube, Instagram, etc.)</td></tr>
<tr><td>Instructional Materials</td><td>Software/Computer Base Training</td></tr>
<tr><td>Internet Promotion</td><td>Speeches and presentations</td></tr>
<tr><td>Published Journal Articles</td><td>Sponsored banner ads</td></tr>
<tr><td>Labeling</td><td>Description of surgical techniques</td></tr>
<tr><td>Market Access Materials, including Payer materials, presentations and programs, and product reimbursement materials</td><td>Wall Charts</td></tr>
<tr><td>Medical Education Materials</td><td>Websites</td></tr>
<tr><td>Meeting Announcements / Invitations</td><td>Advisory Board</td></tr>
<tr><td>Market Research</td><td></td></tr>
</table>

NOTE: Examples of materials not in-scope of this procedure include, but are not limited to:

Contracts
Price lists without product or company branding
Compliance and Quality Management System training
Product Referencing communications to employees.

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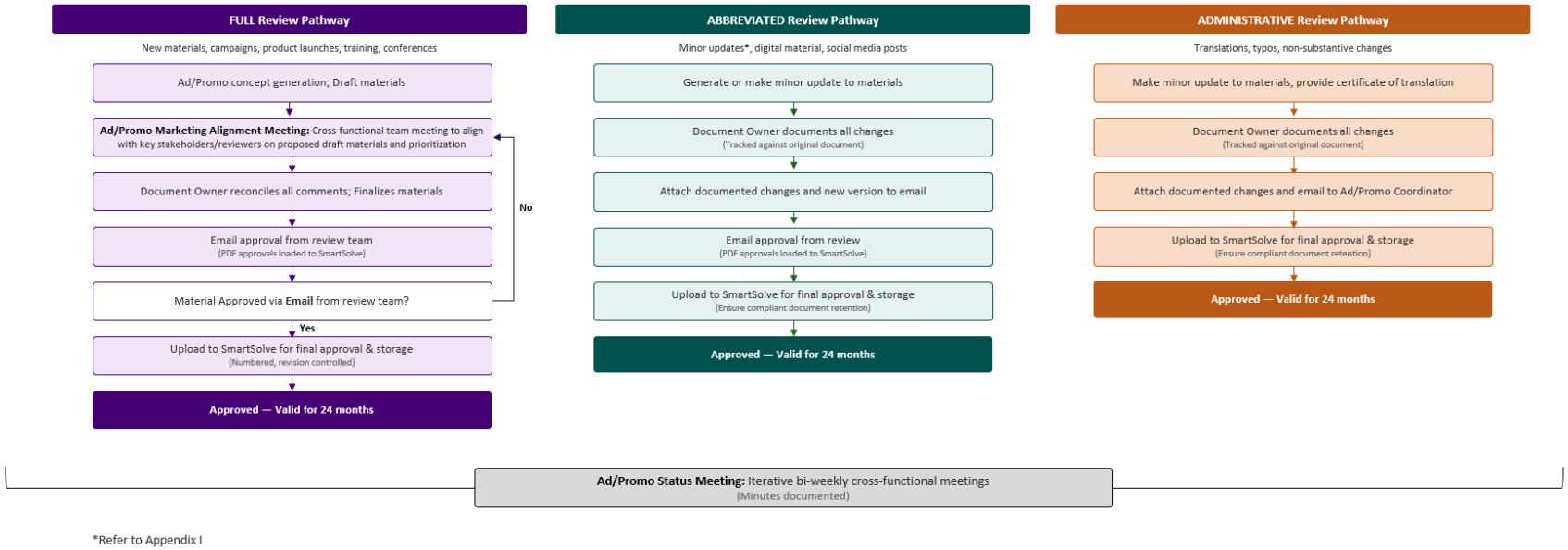
</table>

Term	Definition
	• Clinical recruitment aids that do not promote Bioventus or a product
Solicited / Unsolicited Request for Off-label Information	Requests for off-label information that are prompted in any way by a manufacturer or its representatives are referred to as Solicited Requests. Unsolicited requests are those initiated by persons or entities that are completely independent of Bioventus. Unsolicited requests may be non-public, i.e. directed privately to a firm using one-on-one communication. Public unsolicited requests are made in a public forum, whether directed to a company directly or to a public forum, e.g. social media chat room.
Bioventus Websites	Bioventus' internet web sites: e.g., Bioventus.com are considered labeling.
SmartSolve	Electronic Document Management System (EDMS)

7. Flow chart



*Refer to Appendix I

8. Procedure

8.1. General Review and Approval Process

8.1.1. All Materials shall be reviewed and approved by a Cross-Functional Team to ensure compliance with all legal and regulatory requirements and applicable Company policies. It is the responsibility of the Document Owner to ensure that all Materials are approved pursuant to these requirements prior to use or distribution of such materials. The following guidelines ensure consistent creation and review of Materials for legal and regulatory compliance.

8.1.2. Marketing, Sales Education and Medical Education plans conceived as part of strategic planning for the following year shall be communicated to stakeholders as early as possible so that all key stakeholders are aligned and can provide preliminary guidance prior to finalization of content and submission for review.

8.1.3. All Materials will be reviewed within 10 business days of submission, depending on the length/complexity of the materials provided and strict adherence to the requirements of this procedure and process flows documented below. Review and approval of full campaigns or extensive slide decks will not be expedited if the process below has not been followed. Any materials that have not been discussed and prioritized by a Cross-Functional Team prior to uploading for final review are subject to delays in review and approval.

8.1.4. The Material should be consistent with branding guidelines and logos, using updated images and including all reference and reference documents (highlighting specific claim reference) used in support of statements/claims made within the piece. English language source materials provided to external entities responsible for promoting Bioventus products (i.e., distributors) must also undergo Ad/Promo Review.

8.1.5. For all new Materials, a document number from SmartSolve (SMK/TRN-#) is required prior to distribution to reviewers, regardless of pathway.

Document Type	DMS Numbering Convention	Document Naming Convention [DMS Number] [Product] Brief Description] [Market]
Sales & Marketing Market Access	SMK-000000	e.g. SMK-000123 DUROLANE Patient Brochure EU
Training	TRN-000000	e.g. TRN-000456 SUPARTZ FX Injection Video US

8.1.6. All approved Materials will be numbered and version controlled. Materials approved through the Ad/Promo process will expire no later than 24 months (2 calendar years) after the date of original approval. Continued use of Materials beyond 24 months (2 calendar years) post-original approval

requires that the Materials be resubmitted for review and approval prior to circulation. If the Material is to be revised, it is the responsibility of the Document Owner to identify the new revision and to initiate the change order process within the Document Management System (WIN-000226). If the material has been approved and not released it must go through the review process if more than 12 months have passed.

9. Ad/Promo Status Meeting

9.1. Iterative and consistent bi-weekly Cross-Functional Team meetings to provide updates for each product portfolio and maintain consensus and alignment across key stakeholders from concept to Materials generation. Materials will not be reviewed and approved during this meeting.

9.1.1. Owned by Ad/Promo Coordinator; Calendar invite 'Ad/Promo Status Meeting'.

9.1.2. All Marketing Teams will provide and share updates using the 'Ad/Promo Status Meeting Template'.

9.1.3. General outstanding actions and decisions made during meetings shall be documented via official meeting minutes by the Ad/Promo Coordinator and communicated to the team post-meeting via email.

10. Pathways

10.1. There are three Ad/Promo pathways for review and approval (full, abbreviated, and administrative).

10.2. Full Review Pathway

10.2.1. Intended to be utilized for all new and revised materials:

- Marketing
- Sales Education
- Medical Education
- Social Media Campaigns (> 1 post)
- Product Website Content
- Expansive Product Line Campaigns
- Conference Presentations
- Sales Meetings
- Key Opinion Leader (KOL) Presentations
- Booth Content
- Trade Shows
- Patient Testimonials

10.2.2. Full Review Pathway Process Flow

1. Ad/Promo concept generation, usually as part of annual planning, owned by the respective Marketing Lead.
2. Materials are drafted by the Document Owner.

3. **Ad/Promo Marketing Alignment Meeting**: Cross-Functional Team meeting to align, prioritize, and review Ad/Promo concepts and materials with key stakeholders.
    a. Owned by respective Marketing Lead for each product portfolio; Calendar invite ‘Ad/Promo Marketing Alignment: Product Line’.
    b. Document Owner must document and track all changes.
4. Document Owner reconciles all comments from stakeholders and generates clean, finalized Ad/Promo document.
5. Document Owner sends finalized Material to review team via EMAIL for approval.
    a. If materials are NOT approved via email, outstanding pieces should be discussed during ‘Ad/Promo Marketing Alignment Meeting’.
6. Upload of PDF of email approvals and generated materials into the appropriate electronic document management system by Document Owner for final approval and storage to ensure compliant document retention per corporate guidelines.

10.3. Abbreviated Review Pathway

10.3.1. Intended to be utilized for DIGITAL materials:

- One-off email
- A postcard
- A social media post

10.3.1.1. **NOTE:** The ABBREVIATED pathway should not be used to submit more than one social media post; planned social media posts included as part of ongoing or planned campaigns must utilize the FULL Review pathway. This process is limited to DIGITAL pieces intended for social media and does not apply to larger printed pieces or pieces intended to be used for in-person promotion. It also does not apply to pieces, even if urgent, such as correspondence to the field or our customers about recalls or price changes.

10.3.2. Abbreviated Review Pathway Process Flow

1. Generation of (or minor update to) Materials by Document Owner. If material requires minor updates, all changes are tracked by Document Owner.
2. Document Owner provides documented changes and final/clean version of Materials to review team for email approval.
3. Upload of PDF of email approvals and generated materials into the appropriate electronic document management system by Document

Owner for final approval and storage to ensure compliant document retention per corporate guidelines.

10.4. Administrative Review Pathway

10.4.1. This process is limited to administrative changes only; such as typos and translations to previously approved materials.

10.4.2. Translations

10.4.2.1. All approved English language Materials may be directly translated into other languages via the Administrative Review Pathway, provided the translated Material is accompanied by a certificate of translation. All translations should be completed in accordance with corporate translations policy.

10.4.2.2. International distributors may be provided with generic, English language source materials that are reviewed and approved through the Ad/Promo Review Approval Process. Some international distributors are responsible for creating marketing material in their local language and are responsible for ensuring that these materials meet local laws and regulations. Marketing partners are responsible for ensuring these materials are compliant with the applicable Bioventus agreements for circulation in each territory. The responsibilities for the creation and use of these promotional materials in each territory should be clearly defined in the applicable distribution agreement.

10.4.3. Administrative Review Pathway Process Flow

1. Minor update (typos) to Materials or certificate of translation acquired by Document Owner. All changes are tracked by Document Owner.
2. Document Owner provides documented changes and final/clean version of Materials to Ad/Promo Coordinator for review and approval.
3. Upload of PDF of email approvals and generated materials into the appropriate electronic document management system by Document Owner for final approval and storage to ensure compliant document retention per corporate guidelines.

11. Guidance

11.1. Guidance for document stakeholders and approvers is provided in Appendix 1.

Table 1: Summary of regulatory requirements for advertising and promotional materials

Applicability	Requirements
All devices, regardless of audience	Promotional materials may not promote an unapproved intended use. Promotional materials shall not be false or misleading. Statements/claims within promotional materials must be: • Truthful.

	• Substantiated with adequate data/evidence that is referenced accurately. • Presented with “fair balance”, if comparing to other devices. • Consistent with the approved IFU and the documentation supplied to applicable regulatory agencies.

11.2. The approaches that are permitted and not permitted for making comparative claims in advertising and promotional materials is provided in the table below.

Applicability	**Permitted**	**Not Permitted**
General	• Statements must be true and not misleading. • Device comparisons should use the same scales or ratings (e.g., when making comparison of physical specifications or descriptions). • Must have data documented prior to making a comparison claim. • IFU comparisons are acceptable only if those claims or data that make your device look better are not “cherry picked.” • “Apples to apples” comparisons that are fully documented. • Bench data to support performance facts; reference “data on file.”	• Cannot make false or misleading claims about a competitor’s product. • Cannot make comparisons to a product having a broader indication. • Cannot use data from Bioventus published “white-papers,” abstracts, non-peer reviewed or unpublished articles or presentations. • Data from Limited Market Release (LMR) or New Technology Assessments (NTAs) (clinical experience data) that is not published or peer-reviewed. • Cannot manipulate the study data, unless specifically disclosed and explained, such as “survival curve extrapolated” or how a ‘weighted average’ was derived. • Cannot make comparisons based on device “Generation,” (e.g., Competitor’s 2nd Generation device vs. Bioventus’ 4th Generation device).
Applicability	**Permitted**	
When referring to data from head-to-head trials	• Utilize only data published in peer reviewed medical journals and provide journal citation (full publication not abstract). • Must provide honest and straightforward representation of study data, i.e., presentation of all relevant data from studies both in terms of adverse events studied and all subjects. • Must disclose key demographic parameters (e.g., age, gender distribution, sample size, follow-up, device use/ placement, etc.)	

Applicability	Permitted	Not Permitted
Comparative claims when not referring to data from head-to-head trials	• Must provide honest and straightforward representation of study data, i.e., presentation of all relevant data from studies both in terms of adverse events studied and all subjects. • Must disclose key demographic parameters (e.g., age, gender distribution, sample size, follow-up, device use/ placement, etc.). • May draw conclusions based on comparison of adequate data (e.g., exceptional hemodynamics). • Utilize FDA Summary of Safety and Effectiveness Data (SSED) or data published in peer-reviewed medical journals. Additionally, competitive product IFUs and /or clinical data used for promotional purposes by specific competitive comparison product's company can be referenced but should not be the primary data source for comparison. • Must provide journal citations for all data-supported claims.	

11.3. The following table provides additional guidance for promotional materials intended for US audiences or mixed audiences that include US physicians and customers (**NOTE:** Must still meet the general requirements in the tables above).

Type of FDA submission	Guidance
PMA-approved or 510(k)-cleared devices	• Promotional materials: • May state "commercially available." • May use "PMA approved or 510(k) cleared" once to announce the FDA approval/clearance. This is typically in the form of a press release.
Devices pending FDA PMA approval or 510(k) clearance	• Promotional material may be shared if: • Bioventus is not taking or prepared to take commercial orders • If the promotional material complies with the following: ○ prominently displays: "Pending PMA approval/510(k) clearance", ○ does not imply that the product is safe or effective, ○ may describe the device and how it operates, including descriptions of features, ○ does not include comparative claims, and ○ provides "fair balance" of information provided.

Additional guidance for various types of marketing materials is provided in the table below.

Type of material	Guidance
Press releases	• Do not require an FDA disclosure (e.g., a Brief Summary or Rx Only). If a Press Release is to be distributed by the Company after its initial release to the media, it is considered "promotional material."
Testimonials	• Must be accurate and consistent with approval or clearance and comply with all other promotional material requirements per this procedure.

Type of material	Guidance
	• Bioventus must obtain written permission for use of testimonials from user or customer.
Text or charts taken from literature	• Bioventus must appropriately cite information from the publisher/author for all instances where used.
Web Page Promotional pieces	• If we are promoting a device that is only approved in a select number of countries, must add a disclaimer that states: • "This product may not be approved in all geographies"
Reminder pieces	• Do not require any specific FDA disclosures (e.g., a Brief Summary or Rx Only). • (**Examples**: brochures, pamphlets, convention booth graphics and/ or banners that give only the Bioventus product name, and/or drawings/ photographs of the devices, but make no claims)
Other pieces that do make product claims	The following FDA disclosures must be provided: • "Caution: Federal law restricts this device to sale by or on the order of a physician" (or alternatively, "Rx Only" in prominent manner). • (Class II products) "Please review the instructions for use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use." • (Class III products) "Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use." [Followed by an appropriate and summarized indications/ contraindications/ warnings/ adverse events - - which include the most serious and the most common risks associated with the device.] • **Exemption:** For convention booth graphics and/ or banners, if the specific product's IFU are available on the booth table, the booth's graphics and/ or banners are exempted from the full set of requirements and may instead state the abbreviated: • "Rx Only" and "Refer to Instructions for Use".
Patient specific labeling (e.g., patient brochures, direct to consumer)	• Per FDA guidance, the following statement must be provided: • "These materials are not intended to replace your doctor's advice or information. For any questions or concerns you may have regarding the medical procedures, devices and/ or your personal health, please discuss these with your physician."
For products that do not have U.S. marketing authorizations and are	• The following statement shall be used for all product literature: • "Not for sale in the U.S."

Type of material	Guidance
only for distribution outside the U.S.	
For products that have CE Mark approval.	• The following statement can be used for all product with CE Mark approval: • “Product referenced is CE Marked”
Requests for clinical literature	• Prior to distribution of any clinical literature (inside or outside Bioventus), the article must be reviewed by regulatory and clinical.
Internal distribution of clinical literature (or summaries of the literature); e.g., to Bioventus employees for training purposes	• Whether the publication refers to on-label or off-label use of Bioventus products, the article must be reviewed by regulatory and clinical to determine if any adverse events are reported within the article. If there are adverse events referenced, a copy of the article will be provided to Bioventus Post Market Surveillance. • If the publication refers only to on-label use of Bioventus products, the article can be provided to Bioventus employees without restriction. • If the publication refers to off-label use of Bioventus products, this can be provided to Bioventus employees for their education and not for promotional activities, and must include the following disclaimer” • **“**For informational purposes only. Bioventus LLC does not have [state clearance or approval] for [state specific product and/or intended use]. It is illegal to promote this product in this way in the [applicable geography].”
External distribution of clinical literature (or summaries of the literature); e.g., to physicians	<u>On-label use</u> • The publication must be truthful and not misleading • The Bioventus device mentioned in the article must have received FDA clearance (for distribution to US physicians) • The clinical use described in the article is within the IFU indications <u>Off-label use</u> • It is prohibited to solicit requests for off-label information • Medical Affairs department is authorized to respond to unsolicited off-label requests regarding use of Bioventus products by providing clinical literature; consistent with the Medical Information Request Form (MIRF).

12. APPENDIX 1. Guidance For Reviewer and Approver Selection

Material Content	Cross Functional Stakeholder Review and Resolution Prior To Approval (Reference Responsibilities Table)	Approvers Through Email and SmartSolve
FULL PATHWAY		
• New product • New indication • New laws & regulations • New company policies & procedures • New claim • Competitive comparisons • Promotional giveaways or incentives If the following is included: • Reimbursement	• Document Owner • Marketing • Regulatory • Legal • Creative Services • Compliance If not already included, add: • Market Access • Clinical	Email • Document Owner • Marketing • Creative Services • Regulatory • Legal • Compliance • Clinical (as needed) SmartSolve • Document Owner • Regulatory • Configuration Analyst
• Medical Education Content	• Document Owner • Medical Education • Regulatory • Legal • Marketing • Creative Services • Compliance	Email • Document Owner • Legal • Compliance • Regulatory • Marketing • Medical Education • Creative Services SmartSolve • Document Owner • Regulatory • Configuration Analyst
• Sales Education Content	• Document Owner • Sales Education • Creative Services • Regulatory • Compliance • Legal • Marketing	Email • Document Owner • Regulatory • Legal • Compliance • Marketing • Creative Services SmartSolve • Document Owner • Regulatory • Configuration Analyst
• Change of pictures • New marketing imagery	• Document Owner • Regulatory • Marketing • Creative Services • Legal	Email • Document Owner • Regulatory • Legal • Marketing

Material Content	Cross Functional Stakeholder Review and Resolution Prior To Approval (Reference Responsibilities Table)	Approvers Through Email and SmartSolve
	• Compliance	• Creative Services • Compliance SmartSolve • Document Owner • Regulatory • Configuration Analyst
• Additional product name added to approved material • New references	• Document Owner • Marketing • Clinical • Regulatory • Legal	Email • Document Owner • Marketing • Regulatory • Legal • Creative Services • Clinical SmartSolve • Document Owner • Regulatory • Configuration Analyst
• Social media campaign (> 1 post)	• Document Owner • Marketing • Clinical • Regulatory • Legal • Compliance	Email • Document Owner • Marketing • Regulatory • Legal • Creative Services • Compliance SmartSolve • Document Owner • Regulatory • Configuration Analyst
ABBREVIATED PATHWAY		
• Digital material • Single, social media post	• Document Owner • Marketing • Regulatory • Legal • Compliance	Email • Document Owner • Regulatory • Legal • Creative Services • Compliance SmartSolve • Document Owner • Regulatory • Configuration Analyst
• Approved material to be used in new geographic region	• Document Owner • Marketing • Regulatory • Legal	Email • Document Owner • Regulatory • Legal • Creative Services

Material Content	Cross Functional Stakeholder Review and Resolution Prior To Approval (Reference Responsibilities Table)	Approvers Through Email and SmartSolve
		SmartSolve • Document Owner • Regulatory • Configuration Analyst

• Minor updates including, but not limited to
  ○ Product images with SKUs
  ○ Nomenclature based on region
  ○ QR codes
	• Document Owner
	• Marketing
	• Regulatory
	• Legal
		Email
		• Document Owner
		• Regulatory
		• Legal
		• Creative Services
		SmartSolve
		• Document Owner
		• Regulatory
		• Configuration Analyst

• Claims approved within the previous 2 years • Change of logos in accordance with approved Bioventus guidelines	• Document Owner • Regulatory • Marketing	Email • Document Owner • Regulatory • Creative Services SmartSolve • Document Owner • Regulatory • Configuration Analyst
ADMINISTRATIVE PATHWAY		
• Translation with certificate of translation of an existing approved material	• Document Owner • Marketing • Ad/Promo Coordinator (Regulatory)	Email • Document Owner • Ad/Promo Coordinator (Regulatory) SmartSolve • Document Owner • Ad/Promo Coordinator (Regulatory) • Configuration Analyst
• Re-sizing of an existing approved material to be used for the same purpose	• Document Owner • Marketing • Ad/Promo Coordinator (Regulatory)	Email • Document Owner • Ad/Promo Coordinator (Regulatory) SmartSolve • Document Owner • Ad/Promo Coordinator (Regulatory) • Configuration Analyst
• Repositioning of graphics • Change of address • Spelling correction/typo	• Document Owner • Marketing	Email • Document Owner

Material Content	Cross Functional Stakeholder Review and Resolution Prior To Approval (Reference Responsibilities Table)	Approvers Through Email and SmartSolve
• International phone numbers (excluding customer care, complaints, etc.) • Updating point of contact in approved material	• Ad/Promo Coordinator (Regulatory)	• Ad/Promo Coordinator (Regulatory) SmartSolve • Document Owner • Ad/Promo Coordinator (Regulatory) • Configuration Analyst