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| **1. LABELING INFORMATION** | | | | | | |
| **Product:** |  | **Product Code(s):** | |  | | |
| **Changes Initiated By:** |  | **Date:** | |  | | |
| **Type of Request:** | New Labeling  Changes to Existing Labeling | | | | | |
| **Type(s) of Labeling:** | Product Label  Packaging  Operating Manual/Package Inserts  Marketing Materials  Other: | | | | | |
| **Description of Changes:** | **(Brief description of labeling, proposed changes, and rationale for changes as applicable.)** | | | | | |
| **Impacted Documents:** Title | | | Doc ID | | Rev |
|  | | |  | |  |
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|  | | |  | |  |
| **2. REVIEWS** | | | | | | |
| **SALES & MARKETING REVIEW** | | | | | | |
| Items Considered: 1) Materials are effective and complete for intended use; 2) Materials meet the needs of the intended markets; 3) All claims are substantiated by data on file within the company; 4) Materials are professional and aligned with company mission and values; 5) Any written notification requirements for internal personnel. | | | | | | |
| Comments: | | | | | | |
| Marketing Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| **OPERATIONS/ENGINEERING REVIEW** | | | | | | |
| Items Considered: 1) Illustrations are technically accurate; 2) Procedures described are safe and effective. | | | | | | |
| Comments: | | | | | | |
| Ops/Engineering Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| **OPERATIONS REVIEW** | | | | | | |
| Items Considered: 1) Technical specifications and service requirements (as applicable) and part #’s are correct; 2) Procedural information is accurate and complete. | | | | | | |
| Comments: | | | | | | |
| Ops Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| **REGULATORY & QUALITY REVIEW** | | | | | | |
| Items Considered: 1) All regulatory requirements are met; 2) Adequate warnings are provided for potential hazardous situations | | | | | | |
| Comments: | | | | | | |
| QA/RA Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| **EXTERNAL REVIEW (if Applicable)** | | | | | | |
| Comments: | | | | | | |
| External Representative and Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |