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ChatMD Policy and Procedure for FDA Compliance

Labeling and Packaging

Objective: Ensure compliance with FDA regulations for labeling and packaging of the ChatMD medical device, owned by ChatMD and developed by Smart Data Inc. as the outsourced engineering partner.

1. Policy Statement

Policy: ChatMD shall adhere to FDA regulations regarding labeling and packaging to ensure the safe and effective use of the ChatMD medical device.

2. Protocol and Procedure

2.1 Labeling Requirements

Device Identification

1. **Device Name:**
    - Ensure clear and prominent display of the ChatMD product name, reflecting its intended use and ownership by ChatMD.
2. **Model Identification:**
    - Include specific model or version details of ChatMD as applicable.

Manufacturer Information

1. **Manufacturer Details:**
    - Provide information about ChatMD as the owner and Smart Data Enterprises Inc. as the development partner responsible for engineering and software.
    - Include ChatMD's name, address, and contact information for consumer-facing inquiries related to the ChatMD device.

Instructions for Use

1. **Clear and Concise Instructions:**

- Provide detailed instructions for using the ChatMD medical device safely and effectively.
- Include guidance on setup, operation, maintenance, and troubleshooting specific to the device's functionality.

Warnings and Precautions

1. **Necessary Warnings:**
   - Identify potential risks associated with the use of the ChatMD device.
   - Clearly state warnings and precautions to mitigate risks and ensure user safety.

2.2 Procedure Implementation

Design and Review Process

1. **Collaborative Design:**
   - Collaborate with Smart Data Enterprises Inc. to develop labeling content that meets FDA regulations and accurately represents the ChatMD device.
2. **Content Review:**
   - Conduct a comprehensive review of labeling content by regulatory affairs, legal, and quality assurance teams to ensure accuracy and compliance.

Labeling Approval and Documentation

1. **Approval Process:**
   - Obtain approval for labeling content from ChatMD's regulatory authority, considering input from Smart Data Enterpries Inc. as the development partner.
   - Maintain records of approval and revisions to labeling content.

Printing and Distribution

1. **Printing Specifications:**
   - Ensure labels are printed with durable materials and legible fonts to maintain clarity and compliance with FDA requirements.

- Include necessary identifiers or tracking information for traceability of ChatMD device versions.

2. **Consumer-Facing Distribution:**

   - Ensure consumer-facing platforms and materials (e.g., website, user manuals) reflect accurate and compliant labeling information.
   - Provide digital access to labeling within the ChatMD platform, ensuring updates and revisions are managed effectively.

Monitoring and Updating

1. **Compliance Monitoring:**

   - Regularly audit labeling practices to verify ongoing compliance with FDA regulations and internal standards.
   - Address any discrepancies or non-conformances through corrective and preventive actions (CAPA).

2. **Labeling Updates:**

   - Implement a process to update labeling as necessary due to changes in regulatory requirements, device updates, or user feedback.
   - Maintain version control and ensure obsolete labeling versions are properly archived or withdrawn from circulation.