[Your Name/Organization]
[Your Department]
[Your Address]
[Your Phone Number]
[Your Email]

[Date]

[Recipient Name]
[Recipient Title/Regulatory Agency Name]
[Department/Division]
[Recipient Address]

RE: REFERRAL FOR [PRODUCT NAME/NUMBER] - [SUBMISSION TYPE: E.G., NDA/BLA/MAA]

Dear [Recipient Name/Title],

We are writing to formally refer the regulatory dossier for **[Product Name]** ([Active Ingredient]) for your review and evaluation. This referral is being submitted in accordance with [Reference Specific Regulation or Procedure, e.g., Directive 2001/83/EC Article 31].

Submission Context:
The purpose of this referral is to [Briefly state purpose, e.g., harmonize safety data, resolve divergent decisions, or seek centralized scientific opinion]. The initial application was filed in [Original Jurisdiction] on [Date].

Product Details:

- **Generic Name:** [Name]
- **Dosage Form:** [Form]
- **Indication:** [Indication]
- **Tracking Number:** [Reference Number]

Accompanying Documentation:
Included with this letter are the following supporting materials:
â€¢ [Document 1: e.g., Clinical Overview]
â€¢ [Document 2: e.g., Risk Management Plan]
â€¢ [Document 3: e.g., Summary of Product Characteristics]

We confirm that all electronic files have been scanned for viruses and are compliant with [eCTD/Regional Agency] formatting standards. Should you require further clarification or additional data, please contact our Regulatory Affairs Liaison at [Phone/Email].

Sincerely,

[Signature]
[Printed Name]
[Title]
[Company Name]