Date: [Date]

To: [Physician Name]
[Institution Name]
[Address]

Subject: Approval for Single Patient Compassionate Use (Expanded Access)

Dear Dr. [Physician Last Name],

We are writing to formally notify you that [Company Name] has approved your request for the compassionate use of [Investigational Drug/Device Name] for your patient, [Patient Initials or ID Number].

This approval is granted under the following conditions:

- **Regulatory Authorization:** This approval is contingent upon receiving the necessary authorization from the [Regulatory Authority, e.g., FDA/EMA] and your Institutional Review Board (IRB), where applicable.
- **Indication:** Use is strictly limited to the treatment of [Specific Medical Condition] for this single patient only.
- **Informed Consent:** You must obtain and maintain a signed Informed Consent Form from the patient or their legal guardian prior to treatment.
- **Safety Reporting:** You are required to report all Serious Adverse Events (SAEs) to [Company Name] within 24 hours of discovery.
- **Data Collection:** Brief clinical summaries regarding treatment progress and outcomes must be submitted to the company every [Number] months.

The product will be shipped to your attention at the address provided above once all regulatory documentation has been verified. Please note that [Company Name] is providing this product on a [Gratis / Cost-recovery] basis.

If you have any questions regarding the protocol or shipping logistics, please contact [Contact Person Name] at [Phone/Email].

Sincerely,

[Signature]
[Name of Authorized Official]
[Title]
[Company Name]