<table>
<tr><td colspan="6">Attachment 1: Application form for Lot Release Procedures of Biologics</td></tr>
<tr><td rowspan="2">Applicant</td><td colspan="2">Firm name</td><td>（stamp）</td><td>Representative</td><td>（sign and stamp）</td></tr>
<tr><td colspan="2">Address</td><td rowspan="2"></td><td>Telephone</td><td></td></tr>
<tr><td colspan="2"></td><td>Apply for biologics</td><td>Certificate of Lot Release of Biologics(Copies)：___
Lot Release Certificate (for exportation)(Copies)：_____</td></tr>
<tr><td rowspan="8">Drug that apply for inspecting and batch-sealing</td><td colspan="2">Product name (Chinese)</td><td></td><td>Drug Permission number</td><td></td></tr>
<tr><td colspan="2">Product name (English)</td><td></td><td>Lot number</td><td></td></tr>
<tr><td colspan="2">Ingredients and Strength</td><td></td><td>Expiry Date</td><td></td></tr>
<tr><td colspan="2">Type of container</td><td></td><td>Storage temperature</td><td></td></tr>
<tr><td rowspan="2">Original Manufacturer</td><td>Company name</td><td></td><td>Importation Date</td><td>Year Month Date</td></tr>
<tr><td>Address</td><td colspan="3"></td></tr>
<tr><td colspan="2">Import Amount
Manufacture</td><td></td><td>Batch-sealing / Export
Drug Approval Seal</td><td>Amount</td></tr>
<tr><td>Required documentation</td><td colspan="5">(1)Importing Packing list (Not apply to domestic products).
(2)Lot Release certificate issued by the health authority of country of origin.(Not apply to domestic products).
(3)Drug approval license or a copy of the approval document from the central competent health authority.
(4)Documents of the manufacturing processes, testing methods, specifications, and standards of the biologics and related literatures.
□：If the documents from the original manufacturer are identical to those being recognized during previous process of applying for drug approval license, item(4) can be waived.
(5)Standard operating procedures (SOP) of source management on animal–derived materials and proof of source of derived materials.
□：If the documents from the original manufacturer are identical to previous application, item(5) can be waived.
(6)Summary protocol of biologics during manufacture processes, and testing records and the certificate of analysis of finished products.
□:If the biologics are used for prevention of epidemic disease or exportation, the submission of item(6) can be postponed until the date before the release (permission from the central competent authority is required).</td></tr>
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