

生物藥品檢驗封緘作業辦法第五條附件二、附件三修正對照表

修正規定	現行規定	說 明
<p style="text-align: center;">附件二、生物藥品封緘證明書</p> <div style="text-align: center; padding: 20px;"> <p><u>衛生福利部食品藥物管理署</u> 生物藥品封緘證明書</p> <p style="margin-top: 20px;"><u>FDA 研字第 0000000000 號</u></p> <p style="margin-top: 20px;"><u>申請廠商:</u> 000 <u>製劑名稱:</u> 000 <u>製造廠名:</u> 000 <u>批號:</u> 000 <u>有效日期:</u> 000 <u>包裝:</u> 000 <u>封緘數量:</u> 000 <u>封緘劑量:</u> 000</p> <p style="margin-top: 20px;"><u>上述生物藥品之封緘檢驗案，符合生物藥品檢驗封緘作業之規定，予以封緘，此證。</u></p> </div>	<p style="text-align: center;">附件二、生物藥品封緘證明書</p> <div style="text-align: center; padding: 20px;"> <p><u>行政院衛生署食品藥物管理局</u> 生物藥品封緘證明書</p> <p style="margin-top: 20px;"><u>FDA 研字第 0000000000 號</u></p> <p style="margin-top: 20px;"><u>申請廠商:</u> 000 <u>製劑名稱:</u> 000 <u>製造廠名:</u> 000 <u>批號:</u> 000 <u>有效日期:</u> 000 <u>包裝:</u> 000 <u>封緘數量:</u> 000 <u>封緘劑量:</u> 000</p> <p style="margin-top: 20px;"><u>上述生物藥品之封緘檢驗案，符合生物藥品檢驗封緘作業之規定，予以封緘，此證。</u></p> </div>	<p>因應行政院組織改造，將「行政院衛生署食品藥物管理局」修正為「衛生福利部食品藥物管理署」，將「局長」修正為「署長」。</p>

署長 ○○○

中華民國 年 月 日

局長 ○○○

中華民國 年 月 日

附件三、外銷用生物藥品批次放行證明書



衛生福利部食品藥物管理署

Food and Drug Administration, Ministry of Health and Welfare

地址：11561 臺北市南港區昆陽街 161-2 號 TEL：(02)2787-8000
161-2, Kunyang St. Nangang, TAIPEI, 11561, TAIWAN (R.O.C.) http://www.fda.gov.tw

LOT RELEASE CERTIFICATE

No. TFDA-RA-XXXXXXXXXX

MMM. DD, YYYY

The lot referenced below meets the national requirements for lot release and conforms to the approved specifications. The lot has been tested on the basis of critical evaluation of the manufacture's production and control protocols and on the basis of the evaluation of samples at the Food and Drug Administration.

附件三、外銷用生物藥品批次放行證明書

No.161-2, Kunyang St., Nangang District,
Taipei 115-61, Taiwan (R.O.C)
TEL：886-2-27878000



食品藥物管理局
Food and Drug Administration

Food and Drug Administration

Department of Health, Executive Yuan, Republic of China

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因應行政院組織改造，將「行政院衛生署食品藥物管理局」修正為「衛生福利部食品藥物管理署」，並增加

Product trade name
Common name
Lot number
Expiry date
Number of containers
Number of doses per container
Type of container
Dosage form
Strength of the product
Name and address of manufacturer

Signed by

Director, Division of Research and Analysis

Under the delegated authority of

Director-General
Food and Drug Administration
Ministry of Health and Welfare,
Republic of China

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Republic of China

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訊。