

دليل استرشادي لمتغيرات المستحضرات البشرية تحت التسجيل

طبقا للقرار الوزاري 425

<b><u>Types of Modifications</u></b>	<ul style="list-style-type: none"><li>• Modification of registration request approval</li><li>• Changing applicant for under-registration human pharmaceuticals</li><li>• Changing License Holder for Under-Registration Human pharmaceutical product</li></ul>
<b><u>Submitted to Administration/Unit</u></b>	Evaluation unit of Registration requests for human pharmaceuticals
<b><u>Link for submission</u></b>	<a href="https://forms.gle/u9XrDhDNMeUWdfya9">https://forms.gle/u9XrDhDNMeUWdfya9</a>
<b><u>Steps</u></b>	<p><b>Procedure:</b></p> <p>1-Company submit the request through the following Google link: <a href="https://forms.gle/u9XrDhDNMeUWdfya9">https://forms.gle/u9XrDhDNMeUWdfya9</a></p> <p>2- Submission Review for the request &amp; sending e-mail to the companies with the initial status of the requests:</p> <ul style="list-style-type: none"><li>• Under- revision: The request has fulfilled the requirements &amp; will undergo further revision.</li><li>• Rejected: The request did not fulfill the requirements (the company could re-submit the request after fulfilling the requirements using the same receipt).</li></ul> <p>3-Evaluation of the under- revision request with all its attachments according to the Guidance for modification of registration request approval &amp; Guidance for changing applicant for under-registration human pharmaceuticals &amp; Guidance for Submission for Changing License Holder for Under-Registration Human pharmaceutical product</p> <p>4-If any of the attachments is missed, ask the company to fulfill it by sending the company an e-mail.</p> <p>5- Release the Approval</p>
<b><u>Attachements</u></b>	<ul style="list-style-type: none"><li>-Guidance for modification of registration request approval</li><li>- Guidance for changing applicant for under-registration human pharmaceuticals</li><li>- Guidance for Submission for Changing License Holder for Under-Registration Human pharmaceutical product</li></ul>

<b><u>Types of Modifications</u></b>	<ul style="list-style-type: none"><li>Change in manufacturing site</li></ul>
<b><u>Submitted to Administration/Unit</u></b>	<b>Follow Up Unit For Human Pharmaceuticals</b>
<b><u>Link for submission</u></b>	<a href="https://docs.google.com/forms/d/e/1FAIpQLSdDqiFGdiVsshutf5vM-INpmYeco4ax7wwNUFRlLvLZ7CMPNg/viewform">https://docs.google.com/forms/d/e/1FAIpQLSdDqiFGdiVsshutf5vM-INpmYeco4ax7wwNUFRlLvLZ7CMPNg/viewform</a>
<b><u>Steps</u></b>	<p><b><u>Steps required For changing Manufacturing site for pharmaceutical products under registration:</u></b></p> <p>1- Receiving the request from the company according to the attached Check List and sending it through the following link <a href="https://docs.google.com/forms/d/e/1FAIpQLSdDqiFGdiVsshutf5vM-INpmYeco4ax7wwNUFRlLvLZ7CMPNg/viewform">https://docs.google.com/forms/d/e/1FAIpQLSdDqiFGdiVsshutf5vM-INpmYeco4ax7wwNUFRlLvLZ7CMPNg/viewform</a></p> <p>2- Check the request ensuring the availability of the production line in the new factory, and documenting all contracts and concessions (تتازلات) from the Legal Affairs.</p> <p>3- If the company does not submit a concession from the old factory, the Central Operations Department will be contacted to make a record of the termination of the manufacturing contract.</p> <p>4- Issuing a letter to the company approving the transfer of the manufacturing site for the product under registration, according to the documents submitted by the company after being approved by the Legal Affairs Department of the Egyptian Drug Authority.</p>
<b><u>Attachements</u></b>	-Checklist