**نموذج طلب إلغاء تسجيل مستحضر**

**Permanent Cessation of Marketing of a Medicinal Product**

All fields are mandatory

|  |  |
| --- | --- |
| Date of publication  | 13 September 2020  |
| Version no. | 1 |

*For inquiries:*

Sdr.Drug@sfda.gov.sa

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| --- |
| **Product Information** |
| **Trade Name**  |  | **Reg. no.** |  |
| **Active Ingredient(s)** |  |
| **Route(s) of Administration** |  | **Dosage Form** |  |
| **Package Size and Type** |  | **Strength/Unit** |  |
| **Marketing Authorization Holder (MAH)** |  | **Price** |  |
| **Name and Site of Manufacturer** |  | **Agent** |  |
| **Reason(s) for cessation** |
| □ Production line shutdown | □ Product have not been marketed since first registration |
| □ Low price | □ Product have not been marketed since ……………… |
| □ Increased production expenses | □ Problems in manufacturing |
| □ MAH changed (resourced) | □ Reported adverse events |
| □ Low demand of the product | □ Availability of another pack size of the product, specify |
| □ Manufacturer changed, specify with address | □ Availability of another concentration of the product, specify  |
| □ MAH changed, specify with address | □ Availability of other alternatives marketed by other MAH, specify |
| Other: |
| **Did you attach an official letter from MAH with all required information (The letter should contain a justification for cessation request)** **If not, a justification for not attaching should be provided:** | Yes |
| No |
|  |
| **Amount of product imported to Saudi Arabia during the last four years** |
| **Year** | **20..** | **20..** | **20..** | **20..** |
| **Amount** |  |  |  |  |
| **List of countries that the product is still marketed in:** |
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| **List of countries that ceased the product with dates and reasons for cessation** |
| **Country** | **Date** | **Reasons** |
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