Documents for the elimination of plant requirement in Mexican territory

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Elimination of plant requirement in Mexico

It was established that the applicant to a marketing authorization should demonstrate that have a laboratory or pharmaceutical manufacturing plant in Mexican territory.

« It was eliminated the plant requirement in Mexico territory»

Amendment to Art. 168 of Health Supplies Regulation (RIS).
Official Gazette (DOF) August 5, 2008.

Elimination of plant requirement in Mexico territory

To be a marketing authorization holder is required to have a sanitary license for the manufacturing plant or drugs laboratory or biological products for human use.

In the case of foreign manufacturers are required to have a license, certificate or document certifying that the company has a license to manufacturing drugs, issued by the competent authority in the country of origin.

Amendment to Art. 168 of Health Supplies Regulation (RIS).
Official Gazette (DOF) August 5, 2008.

Elimination of plant requirement in Mexico

Problems detected in the submission (examples):

- The applicant for marketing authorization holder, has no license or document according Article 168 of RIS.
- The address of the manufacturer of the drug that is expressed in the draft labels has a change of manufacturing or conditioning.
- There is substitution of the manufacturer or holder.
- The draft labels corresponding to different presentation or strengths previously authorized.

Elimination of plant requirement in Mexico

Problems detected in the submission (examples:

- There are changes in prescribing information: extended or modification of label, adverse events, route, dosing, etc.
- The storage conditions are different from the previously authorized.
- Do not include the latest versions of approved projects of label
- Do not include the product free sales certificate or the formula do not match with the previously authorized.
- The license or document as manufacturer is not legalized.

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It is acceptable:

- Certified copy of license, certificate or document certifying that the company has the license for manufacturing drugs issued by the competent authority of the country of origin, legalized or apostilled, translated to Spanish by an expert authorized translator in Mexico.
- Certificate of Good Manufacturing Practices for the national or foreign manufacturers (total and/or partial).
- Free Sales Certificate or CPP. Legalized and translated to Spanish.
- Document that certifies the Legal Representative in Mexico.
  - It is recommended wide representation power or general representation with at least 5 years
  - Legalized

Elimination of plant requirement in Mexico

It is acceptable:

- Pharmacovigilance Unit approved by the National Center of Pharmacovigilance (Centro Nacional de Farmacovigilancia).
- Official letter for authorization issued by National Center of Pharmacovigilance of COFEPRIS.
- Imported bulk products may be packed in Mexico where the jobber must have a valid sanitary license and have the authorization of the production line for the pharmaceutical form.
- In case of conditioning of penicillin, cephalosporin, viral or bacterial biological and blood products, must have a specific and independent areas for each one of them, in order to prevent the cross-contamination with other manufacturing areas. Must have the sanitary license for controlled drugs.

Elimination of plant requirement in Mexico

It is acceptable:

- In the case of secondary conditioning, is required the license for conditioning or packing of the pharmaceutical products.
- For non-controlled drug distribution is required the functioning notice to COFEPRIS.
- States the locations and / or address of the warehouse or the responsible facility.
- States in the labels, the importer, distributor and / or conditioner when it was not the same manufacturer of the drug.
- Signed contract with Authorized Third Party for release analysis (when the importer or legal representative is not a filial company).
    - Analysis is not accepted between persons or companies. It must be an Authorized Third Party.