

Mechanism of Fast Track Regarding the Stability Files

Year 2023

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Updating the mechanism of fast track regarding the stability files issued in April, 2021.

In view of the great efforts made by the General Administration of Stability and in view of its continuous keenness to keep pace with the development of the pharmaceutical industry, increase the investments targeting the pharmaceutical industry field and enhance the production inside and outside the country, the mechanism of the **stability fast track** was decided.

The executive mechanism of the decision is as follows:

The company submits a maximum of 3 applications every Monday, provided that each application shall be for one of the following different purposes:

1. Accelerating the procedures of reviewing and evaluating stability studies, where such procedures and evaluating shall done within a period of 10 working days from the receiving date of the complete stability study dossier.
2. Increasing the number of stability study files submitted to obtain an appointment in order to exceed the limit permitted for each company per month.
3. Increasing the number of petitions uploaded on the petitions link of Administration Stability of each Mondays and Thursdays for local products and each Wednesdays for imported products every week.

Each product application shall include the following:

1. Payment receipt for the service.
2. A letter from the company stating the product name, company name and the product status in term of taking a new appointment to review the stability study file or to obtain an appointment for completing a stability study that had been previously reviewed.

The competent pharmacist shall review the documents and set an appointment to upload the file within one day from the date of receiving the complete application to the following email :

stability.reception@edaegypt.gov.eg

stability.imported@edaegypt.gov.eg

The following shall be taken into consideration:

1. Booking shall be on Sunday at the following link:
<https://docs.google.com/forms/d/e/1FAIpQLSfbqftu8hXlx2vquk5VZilshGWCWMsV45AujMNcuBa19-YrcA/closedform>
2. The number of applications allowed for each company is three per week, provided that each request shall be for one of the different purposes previously described.
3. Receiving the applications of the fast track system shall be carried out after obtaining an appointment to receive the product.
4. A competent pharmacist in the General Administration of Stability shall receive the applications (hard copy) each Monday from 10 A.M to 12 noon in the reception hall on the ground floor.