



Federal Agency for Medicines and Health Products

Department **Registration**

YOUR LETTER FROM

YOUR REF.

OUR REF.

DATE

ANNEX

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Circular letter N° 521

To all Applicants / Marketing Authorization Holders  
for medicinal products of human use

SUBJECT: **INACTIVATION OF FILES IN THE ADMINISTRATIVE FINALISATION PHASE**

**This document is a translation of the official and signed versions in Dutch and French**

Dear Madam, Dear Sir,

At the time of the administrative finalisation of the registration files by the closing unit of the registration department, it appears that:

- some documents needed to the administrative finalisation are missing
- some documents introduced are not in compliance with the AFMPS's requirements.
- some holders do not answer within an acceptable time at the requests of information addressed to them

These failures generate a deceleration in the process of the closure of the files.

To avoid these failures, the registration department of the AFMPS proposes:

- to inform the holders of a marketing authorisation on the documents which must be presented for the administrative finalisation of a file and on the requirements of the AFMPS on the contents of these documents.
- to set up a system of inactivation of the files for which documents would be still missing or not in compliance with our requirements after 2 recalls.

#### **How do we intend to inform the marketing authorisation holders/applicants**

- Via our website with the following address:  
<https://portal.health.fgov.be/portal/page?pageid=56,513152&dad=portal&schemata=PORTAL>
- Via the representatives of pharmaceutical industry
- Via sessions of information



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## Inactivation of the files

At the time of the administrative finalisation of a file and if necessary, a request for supplementary information will be sent by the manager responsible for the administrative finalisation of the file to the contact person mentioned on the application form.

In absence of response or in the case of incomplete response in the 2 weeks which follow the first sending, a first recall is sent.

In absence of response or in the case of incomplete response in the 2 weeks which follow this first recall, a second recall is sent.

In absence of response or in the case of incomplete response in the 2 weeks which follow this second recall, the file is going to be inactivated.

The inactivated files will lose any priority at the administrative finalisation phase. No request for priority introduced to the Center Cal will be taken into account for these files.

It will be reactivated only when the provided documentation will be complete and in compliance with the AFMPS's requirements. It could then be closed.

This system of inactivation will also be applied to the files for which the fee has not been paid.

This system of inactivation will be applied by the unit closing of the registration department from the 09/06/2008. This system does not apply to the drugs notified such as the homeopathic drugs.

Yours sincerely,

Chief executive

Mr. X. De Cuyper

Head of Registration Department

Mr. A. Lhoir