REGULATORY COMPLIANCE ASSOCIATES® INC

Wellness for Business®

Frequently Asked Question

Webinar: Managing Challenging Submissions

Date of Webinar: September 26, 2017

RCA's Panelists: Lisa Michels/Laura Reynolds

How do you know when there's no more requests for additional information?

Lisa Michels: The Lead Reviewer may ask questions or request additional information at the very late stages of the FDA review cycle for any type of submission (510(k); PMA; De Novo). Unfortunately, in the past this practice was quite common. However, over the course of the last several years, this practice is less common due to industry pressure and the MDUFA goals and objectives the FDA sets for itself to comply with the specific review cycles for each of the various types of submissions.

Until you actually receive the Substantially Equivalent (SE) Determination Letter or the Approval Letter from the FDA, do not assume that the Lead Reviewer cannot ask additional questions about your submission.