

§ 152.105

the application. The Agency will review each application to determine whether it is complete. An application is incomplete if any pertinent item specified in §152.50 has not been submitted, or has been incorrectly submitted (for example, data required by part 158 of this chapter not submitted in accordance with the requirements for format, claims of confidential business information, or flagging).

§ 152.105 Incomplete applications.

The Agency will not begin or continue the review of an application that is incomplete. If the Agency determines that an application is incomplete or that further information is needed in order to complete the Agency's review, the Agency will notify the applicant of the deficiencies and allow the applicant 75 days to make corrections or additions to complete the application. If the applicant believes that the deficiencies cannot be corrected within 75 days, he must notify the Agency within those 75 days of the date on which he expects to complete the application. If, after 75 days, the applicant has not responded, or if the applicant subsequently fails to complete the application within the time scheduled for completion, the Agency will terminate any action on such application, and will treat the application as if it had been withdrawn by the applicant. Any subsequent submission relating to the same product must be submitted as a new application.

§ 152.107 Review of data.

(a) The Agency normally will review data submitted with an application that have not previously been submitted to the Agency.

(b) The Agency normally will review other data submitted or cited by an applicant only:

(1) As part of the process of reregistering currently registered products;

(2) When acting on an application for registration of a product containing a new active ingredient;

(3) If such data have been flagged in accordance with §158.34 of this chapter; or

(4) When the Agency determines that it would otherwise serve the public interest.

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(c) If the Agency finds that it needs additional data in order to determine whether the product may be registered, it will notify the applicant as early as possible in the review process.

§ 152.108 Review of labeling.

The Agency will review all draft labeling submitted with the application. If an applicant for amended registration submits only that portion of the labeling proposed for amendment, the Agency may review the entire label, as revised by the proposed changes, in deciding whether to approve the amendment. The Agency will not approve final printed labeling, but will selectively review it for compliance.

§ 152.110 Time for Agency review.

The Agency will complete its review of applications as expeditiously as possible. Applications involving new active ingredients, new uses, petitions for tolerance or exemptions, or consultation with other Federal agencies normally will take longer than applications for substantially similar products and uses.

§ 152.111 Choice of standards for review of applications.

The Agency has discretion to review applications under either the unconditional registration criteria of FIFRA sec. 3(c)(5) or the conditional registration criteria of FIFRA sec. 3(c)(7). The type of review chosen depends primarily on the extent to which the relevant data base has been reviewed for completeness and scientific validity. EPA conducts data reviews needed to support unconditional registrations on a chemical-by-chemical basis, according to an established priority list. Except for applications for registration of a new active ingredient or in special cases where it finds immediate review to be warranted, the Agency will not commence a complete review of the existing data base on a given chemical in response to receipt of an application for registration. Instead the Agency will review the application using the criteria for conditional registration in FIFRA sec. 3(c)(7) (A) and (B).