Section 861.34 Amendment or revocation of a standard.

(a) The Food and Drug Administration will provide for periodic evaluation of performance standards to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.

(b) The Food and Drug Administration may, on its own initiative or upon petition of an interested party, amend this

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within 60 days of the publication of the notice and after consultation with the appropriate panel under §860.125 of this chapter, either deny the request or give notice of its intent to initiate a change in the classification under §860.130.

(d) If FDA initiates a rulemaking proceeding under paragraph (a) of this section, FDA will:

(1) Complete the proceeding and establish the performance standard for the device in accordance with this part and §10.40 of this chapter; or

(2) Terminate the proceeding by publishing in the F EDERAL REGISTER a notice announcing such termination and the reasons therefor and, unless the proceeding is terminated because the device is a banned device, initiate a proceeding in accordance with section 513(e) of the act to reclassify the device; or

(3) Take other appropriate action.