21 U.S. Code § 356a

Manufacturing changes

(a) In general

With respect to a drug for which there is in effect an approved application under section 355 or 360b of this title or a license under section 262 of title 42, a change from the manufacturing process approved pursuant to such application or license may be made, and the drug as made with the change may be distributed, if—

(1) the holder of the approved application or license (referred to in this section as a "holder") has validated the effects of the change in accordance with subsection (b); and

(2)

(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c); or

(B) in the case of a change that is not a major manufacturing change, the holder complies with the applicable requirements of subsection (d).