

21 U.S. Code § 360bbb-8d

Notification, nondistribution, and recall of controlled substances

(a) Order to cease distribution and recall

(1) In general

If the Secretary determines there is a reasonable probability that a controlled substance would cause serious adverse health consequences or death, the Secretary may, after providing the appropriate person with an opportunity to consult with the agency, issue an order requiring manufacturers, importers, distributors, or pharmacists, who distribute such controlled substance to immediately cease distribution of such controlled substance.

(2) Hearing

An order under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on whether adequate evidence exists to justify an amendment to the order, and what actions are required by such amended order pursuant to subparagraph (3).

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