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21 U.S. Code § 382

Exports of certain unapproved products

(a) Drugs or devices intended for human or animal use which require approval or licensing

A drug or device—

(1) which, in the case of a drug—

(A)

(i) requires approval by the Secretary under section 355 of this title before such drug may be introduced or delivered for introduction into interstate commerce; or

(ii) requires licensing by the Secretary under section 262 of title 42 or by the Secretary of Agriculture under the Act of March 4, 1913 [21 U.S.C. 151 et seq.] (known as the Virus-Serum Toxin Act) before it may be introduced or delivered for introduction into interstate commerce;

(B) does not have such approval or license; and

(C) is not exempt from such sections or Act; and

(2) which, in the case of a device—

(A) does not comply with an applicable requirement under section 360d or 360e of this title;

(B) under section 360j(g) of this title is exempt from either such section; or

(C) is a banned device under section 360f of this title, is adulterated, misbranded, and in violation of such sections or Act unless the export of the drug or device is, except as provided in subsection (f), authorized under subsection (b), (c), (d), or (e) or section 381(e)(2) of this title. If a drug or device described in paragraphs (1) and (2) may be exported under subsection (b) and if an application for such drug or device under section 355 or 360e of this title or section 262 of title 42 was disapproved, the Secretary shall notify the appropriate public health official of the country to which such drug will be exported of such disapproval.