

"AUTHORITY TO WITHDRAW APPROVAL OF
ABBREVIATED DRUG APPLICATIONS

"SEC. 308. (a) IN GENERAL.—The Secretary—

"(1) shall withdraw approval of an abbreviated drug application if the Secretary finds that the approval was obtained, expedited, or otherwise facilitated through bribery, payment of an illegal gratuity, or fraud or material false statement, and

"(2) may withdraw approval of an abbreviated drug application if the Secretary finds that the applicant has repeatedly demonstrated a lack of ability to produce the drug for which the application was submitted in accordance with the formulations or manufacturing practice set forth in the abbreviated drug application and has introduced, or attempted to introduce, such adulterated or misbranded drug into commerce.

"(b) PROCEDURE.—The Secretary may not take any action under subsection (a) with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

"(c) APPLICABILITY.—Subsection (a) shall apply with respect to offenses or acts regardless of when such offenses or acts occurred.

"(d) JUDICIAL REVIEW.—Any person that is the subject of an adverse decision under subsection (a) may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside."

SEC. 5. INFORMATION.

Section 505(j) (21 U.S.C. 355(j)) is amended by adding at the end the following:

"(8) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

"(A) the name of the applicant,

"(B) the name of the drug covered by the application,

"(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

"(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application."

SEC. 6. DEFINITIONS.

Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

"(bb) The term 'abbreviated drug application' means an application submitted under section 505(j) or 507 for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and—

"(1) in the case of section 306, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

"(2) in the case of sections 307 and 308, includes any supplement to such an application.

"(cc) The term 'knowingly' or 'knew' means that a person, with respect to information—

"(1) has actual knowledge of the information, or

"(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

"(dd) For purposes of section 306, the term 'high managerial agent'—

"(1) means—

"(A) an officer or director of a corporation or an association,

"(B) a partner of a partnership, or

"(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

"(2) includes persons having management responsibility for—

"(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

"(B) production, quality assurance, or quality control of any drug product, or

"(C) research and development of any drug product.

"(ee) For purposes of sections 306 and 307, the term 'drug product' means a drug subject to regulation under section 505, 507, 512, or 802 of this Act or under section 351 of the Public Health Service Act."

SEC. 7. EFFECT ON OTHER LAWS.

No amendment made by this Act shall preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by this Act.

Amend the title so as to read: "An Act to authorize the Secretary of Health and Human Services to impose debarments and to take other action to ensure the integrity of abbreviated drug applications under the Federal Food, Drug, and Cosmetic Act, and for other purposes."

The SPEAKER pro tempore, Mr. NEAL of North Carolina, recognized Mr. WAXMAN and Mr. BLILEY, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and agree to said amendments?

The SPEAKER pro tempore, Mr. NEAL of North Carolina, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said amendments were agreed to.

A motion to reconsider the vote whereby the rules were suspended and said amendments were agreed to was, by unanimous consent, laid on the table.

Ordered, That the Clerk notify the Senate thereof.

¶44.8 SUBPOENA

The SPEAKER pro tempore, Mr. NEAL of North Carolina, laid before the House a communication, which was read as follows:

HOUSE OF REPRESENTATIVES,

Washington, DC.

DEAR MR. SPEAKER: This is to notify you pursuant to Rule L (50) of the Rules of the House that I have been served with a subpoena issued by the Missouri Circuit Court.

After consultation with the General Counsel to the Clerk, I have determined that compliance with the subpoena is consistent with the privileges and precedents of the House.

Sincerely,

WILLIAM L. CLAY.

¶44.9 SUBPOENA

The SPEAKER pro tempore, Mr. NEAL of North Carolina, laid before the House a communication, which was read as follows:

HOUSE OF REPRESENTATIVES,

Washington, DC, April 22, 1992.

Hon. THOMAS S. FOLEY,

Speaker, House of Representatives, U.S. Capitol Building, Washington, DC.

DEAR MR. SPEAKER: This is to notify you pursuant to Rule L (50) of the Rules of the House that I have been served with a subpoena duces tecum issued by the Blackford County Circuit Court in the State of Indiana. It requests that my office provide informational materials in a legal dispute between two local parties.

After consultation with the General Counsel to the Clerk, I have determined that compliance with the subpoena is consistent with the privileges and precedents of the House.

Sincerely,

PHIL SHARP,
Member of Congress.

¶44.10 SUBPOENA

The SPEAKER pro tempore, Mr. NEAL of North Carolina, laid before the House a communication, which was read as follows:

HOUSE OF REPRESENTATIVES, COMMITTEE ON ENERGY AND COMMERCE, SUBCOMMITTEE ON COMMERCE, CONSUMER PROTECTION, AND COMPETITIVENESS,

Washington, DC, April 6, 1992.

Hon. THOMAS S. FOLEY,

Speaker of the House, U.S. Capitol, Washington, DC.

DEAR MR. SPEAKER: This is to notify you pursuant to Rule L (50) of the Rules of the House that the Subcommittee on Commerce, Consumer Protection, and Competitiveness of the Committee on Energy and Commerce has been served with a subpoena issued by the United States District Court for the Southern District of New York for testimony by a staff member. After consultation with the General Counsel to the Clerk, the attached letter was sent to the court, and the subpoena was withdrawn.

Sincerely,

CARDISS COLLINS,
Chairwoman.

¶44.11 SUBPOENA

The SPEAKER pro tempore, Mr. NEAL of North Carolina, laid before the House a communication, which was read as follows:

HOUSE OF REPRESENTATIVES, COMMITTEE ON STANDARDS OF OFFICIAL CONDUCT,

Washington, DC, April 24, 1992.

Hon. THOMAS S. FOLEY,

Speaker, House of Representatives, Washington, DC.

DEAR MR. SPEAKER: This is to formally notify you pursuant to Rule L (50) of the Rules of the House that the Committee on Standards of Official Conduct has been served with a subpoena issued by the United States District Court for the District of Columbia.

Sincerely,

MATTHEW F. MCHUGH,
Acting Chairman.