Public Law 102-282
102d Congress

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.

May 13, 1992
[H.R. 2454]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Generic Drug Enforcement Act of 1992.

SECTION 1. SHORT TITLE; REFERENCE; FINDINGS; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Generic Drug Enforcement Act of 1992". 21 USC 301 note.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

(c) FINDINGS.—The Congress finds that— 21 USC 335a note.

(1) there is substantial evidence that significant corruption occurred in the Food and Drug Administration's process of approving drugs under abbreviated drug applications,

(2) there is a need to establish procedures designed to restore and to ensure the integrity of the abbreviated drug application approval process and to protect the public health, and

(3) there is a need to establish procedures to bar individuals who have been convicted of crimes pertaining to the regulation of drug products from working for companies that manufacture or distribute such products.

(d) TABLE OF CONTENTS.—

SEC. 2. DEBARMENT AND OTHER RESTRICTIONS.

Sections 306 and 307 (21 U.S.C. 336, 337) are redesignated as sections 309 and 310, respectively, and the following is inserted after section 305:

"DEBARMENT, TEMPORARY DENIAL OF APPROVAL, AND SUSPENSION

21 USC 335a.

"SEC. 306. (a) MANDATORY DEBARMENT.—

"(1) CORPORATIONS, PARTNERSHIPS, AND ASSOCIATIONS.—If the Secretary finds that a person other than an individual has been convicted, after the date of the enactment of this section, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application, the Secretary shall debar such person from submitting, or assisting in the submission of, any such application.

"(2) INDIVIDUALS.—If the Secretary finds that an individual has been convicted of a felony under Federal law for conduct—

"(A) relating to the development or approval, including the process for development or approval, of any drug product, or

"(B) otherwise relating to the regulation of any drug product under this Act,

the Secretary shall debar such individual from providing services in any capacity to a person that has an approved or pending drug product application.

"(b) PERMISSIVE DEBARMENT.—

"(1) IN GENERAL.—The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (2), debar—

"(A) a person other than an individual from submitting or assisting in the submission of any abbreviated drug application, or

"(B) an individual from providing services in any capacity to a person that has an approved or pending drug product application.

"(2) PERSONS SUBJECT TO PERMISSIVE DEBARMENT.—The following persons are subject to debarment under paragraph (1):

"(A) CORPORATIONS, PARTNERSHIPS, AND ASSOCIATIONS.—Any person other than an individual that the Secretary finds has been convicted—

"(i) for conduct that—

"(I) relates to the development or approval, including the process for the development or approval, of any abbreviated drug application; and

"(II) is a felony under Federal law (if the person was convicted before the date of the enactment of this section), a misdemeanor under Federal law, or a felony under State law, or

"(ii) of a conspiracy to commit, or aiding or abetting, a criminal offense described in clause (i) or a felony described in subsection (a)(1),

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

"(B) INDIVIDUALS.—

"(i) Any individual whom the Secretary finds has been convicted of—

"(I) a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under this Act, or

"(II) a conspiracy to commit, or aiding or abetting, such criminal offense or a felony described in subsection (a)(2),

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

"(ii) Any individual whom the Secretary finds has been convicted of—

"(I) a felony which is not described in subsection (a)(2) or clause (i) of this subparagraph and which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or

"(II) a conspiracy to commit, or aiding or abetting, such felony,

if the Secretary finds, on the basis of the conviction of such individual and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this Act relating to drug products.

"(iii) Any individual whom the Secretary finds materially participated in acts that were the basis for a conviction for an offense described in subsection (a) or in clause (i) or (ii) for which a conviction was obtained, if the Secretary finds, on the basis of such participation and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this Act relating to drug products.

"(iv) Any high managerial agent whom the Secretary finds—

"(I) worked for, or worked as a consultant for, the same person as another individual during the period in which such other individual took actions for which a felony conviction was obtained and which resulted in the debarment under subsection (a)(2), or clause (i), of such other individual,

"(II) had actual knowledge of the actions described in subclause (I) of such other individual, or took action to avoid such actual knowledge,

or failed to take action for the purpose of avoiding such actual knowledge,

"(III) knew that the actions described in subclause (I) were violative of law, and

"(IV) did not report such actions, or did not cause such actions to be reported, to an officer, employee, or agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable time after such agent first knew of such actions,

if the Secretary finds that the type of conduct which served as the basis for such other individual's conviction undermines the process for the regulation of drugs.

Effective date.

"(3) STAY OF CERTAIN ORDERS.—An order of the Secretary under clause (iii) or (iv) of paragraph (2)(B) shall not take effect until 30 days after the order has been issued.

"(c) DEBARMENT PERIOD AND CONSIDERATIONS.—

"(1) EFFECT OF DEBARMENT.—The Secretary—

"(A) shall not accept or review (other than in connection with an audit under this section) any abbreviated drug application submitted by or with the assistance of a person debarred under subsection (a)(1) or (b)(2)(A) during the period such person is debarred,

"(B) shall, during the period of a debarment under subsection (a)(2) or (b)(2)(B), debar an individual from providing services in any capacity to a person that has an approved or pending drug product application and shall not accept or review (other than in connection with an audit under this section) an abbreviated drug application from such individual, and

"(C) shall, if the Secretary makes the finding described in paragraph (6) or (7) of section 307(a), assess a civil penalty in accordance with section 307.

"(2) DEBARMENT PERIODS.—

"(A) IN GENERAL.—The Secretary shall debar a person under subsection (a) or (b) for the following periods:

"(i) The period of debarment of a person (other than an individual) under subsection (a)(1) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under subsection (a) occurs within 10 years after such person has been debarred under subsection (a)(1), the period of debarment shall be permanent.

"(ii) The debarment of an individual under subsection (a)(2) shall be permanent.

"(iii) The period of debarment of any person under subsection (b)(2) shall not be more than 5 years.

The Secretary may determine whether debarment periods shall run concurrently or consecutively in the case of a person debarred for multiple offenses.

"(B) NOTIFICATION.—Upon a conviction for an offense described in subsection (a) or (b) or upon execution of an agreement with the United States to plead guilty to such an offense, the person involved may notify the Sec-

retary that the person acquiesces to debarment and such person's debarment shall commence upon such notification.

"(3) CONSIDERATIONS.—In determining the appropriateness and the period of a debarment of a person under subsection (b) and any period of debarment beyond the minimum specified in subparagraph (A)(i) of paragraph (2), the Secretary shall consider where applicable—

"(A) the nature and seriousness of any offense involved,

"(B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

"(C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

"(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

"(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

"(F) prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

"(d) TERMINATION OF DEBARMENT.—

"(1) APPLICATION.—Any person that is debarred under subsection (a) (other than a person permanently debarred) or any person that is debarred under subsection (b) may apply to the Secretary for termination of the debarment under this subsection. Any information submitted to the Secretary under this paragraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

"(2) DEADLINE.—The Secretary shall grant or deny any application respecting a debarment which is submitted under paragraph (1) within 180 days of the date the application is submitted.

"(3) ACTION BY THE SECRETARY.—

"(A) CORPORATIONS.—

"(i) CONVICTION REVERSAL.—If the conviction which served as the basis for the debarment of a person under subsection (a)(1) or (b)(2)(A) is reversed, the Secretary shall withdraw the order of debarment.

"(ii) APPLICATION.—Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of a person if the Secretary finds that—

"(I) changes in ownership, management, or operations have fully corrected the causes of the offense

involved and provide reasonable assurances that the offense will not occur in the future, and

"(II) sufficient audits, conducted by the Food and Drug Administration or by independent experts acceptable to the Food and Drug Administration, demonstrate that pending applications and the development of drugs being tested before the submission of an application are free of fraud or material false statements.

In the case of persons debarred under subsection (a)(1), such termination shall take effect no earlier than the expiration of one year from the date of the debarment.

"(B) INDIVIDUALS.—

"(i) CONVICTION REVERSAL.—If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) or clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B) is reversed, the Secretary shall withdraw the order of debarment.

"(ii) APPLICATION.—Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of an individual who has been debarred under subsection (b)(2)(B) if such termination serves the interests of justice and adequately protects the integrity of the drug approval process.

"(4) SPECIAL TERMINATION.—

"(A) APPLICATION.—Any person that is debarred under subsection (a)(1) (other than a person permanently debarred under subsection (c)(2)(A)(i)) or any individual who is debarred under subsection (a)(2) may apply to the Secretary for special termination of debarment under this subsection. Any information submitted to the Secretary under this subparagraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

"(B) CORPORATIONS.—Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that—

"(i) the person making the application under subparagraph (A) has demonstrated that the felony conviction which was the basis for such person's debarment involved the commission of an offense which was not authorized, requested, commanded, performed, or recklessly tolerated by the board of directors or by a high managerial agent acting on behalf of the person within the scope of the board's or agent's office or employment,

"(ii) all individuals who were involved in the commission of the offense or who knew or should have known of the offense have been removed from employment involving the development or approval of any drug subject to sections 505 or 507,

"(iii) the person fully cooperated with all investigations and promptly disclosed all wrongdoing to the appropriate authorities, and

"(iv) the person acted to mitigate any impact on the public of any offense involved, including the recall, or the discontinuation of the distribution, of any drug

with respect to which the Secretary requested a recall or discontinuation of distribution due to concerns about the safety or efficacy of the drug.

"(C) INDIVIDUALS.—Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that such individual has provided substantial assistance in the investigations or prosecutions of offenses which are described in subsection (a) or (b) or which relate to any matter under the jurisdiction of the Food and Drug Administration.

"(D) SECRETARIAL ACTION.—The action referred to in subparagraphs (B) and (C) is—

"(i) in the case of a person other than an individual—

"(I) terminating the debarment immediately, or

"(II) limiting the period of debarment to less than one year, and

"(ii) in the case of an individual, limiting the period of debarment to less than permanent but to no less than 1 year,

whichever best serves the interest of justice and protects the integrity of the drug approval process.

"(e) PUBLICATION AND LIST OF DEBARRED PERSONS.—The Secretary shall publish in the Federal Register the name of any person debarred under subsection (a) or (b), the effective date of the debarment, and the period of the debarment. The Secretary shall also maintain and make available to the public a list, updated no less often than quarterly, of such persons, of the effective dates and minimum periods of such debarments, and of the termination of debarments.

Federal Register, publication. Public information.

"(f) TEMPORARY DENIAL OF APPROVAL.—

"(1) IN GENERAL.—The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (3), refuse by order, for the period prescribed by paragraph (2), to approve any abbreviated drug application submitted by any person—

"(A) if such person is under an active Federal criminal investigation in connection with an action described in subparagraph (B),

"(B) if the Secretary finds that such person—

"(i) has bribed or attempted to bribe, has paid or attempted to pay an illegal gratuity, or has induced or attempted to induce another person to bribe or pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services or to any other Federal, State, or local official in connection with any abbreviated drug application, or has conspired to commit, or aided or abetted, such actions, or

"(ii) has knowingly made or caused to be made a pattern or practice of false statements or misrepresentations with respect to material facts relating to any abbreviated drug application, or the production of any drug subject to an abbreviated drug application, to any officer, employee, or agent of the Department of Health and Human Services, or has conspired to commit, or aided or abetted, such actions, and

"(C) if a significant question has been raised regarding—

"(i) the integrity of the approval process with respect to such abbreviated drug application, or

"(ii) the reliability of data in or concerning such person's abbreviated drug application.

Such an order may be modified or terminated at any time.

"(2) APPLICABLE PERIOD.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), a denial of approval of an application of a person under paragraph (1) shall be in effect for a period determined by the Secretary but not to exceed 18 months beginning on the date the Secretary finds that the conditions described in subparagraphs (A), (B), and (C) of paragraph (1) exist. The Secretary shall terminate such denial—

"(i) if the investigation with respect to which the finding was made does not result in a criminal charge against such person, if criminal charges have been brought and the charges have been dismissed, or if a judgment of acquittal has been entered, or

"(ii) if the Secretary determines that such finding was in error.

"(B) EXTENSION.—If, at the end of the period described in subparagraph (A), the Secretary determines that a person has been criminally charged for an action described in subparagraph (B) of paragraph (1), the Secretary may extend the period of denial of approval of an application for a period not to exceed 18 months. The Secretary shall terminate such extension if the charges have been dismissed, if a judgment of acquittal has been entered, or if the Secretary determines that the finding described in subparagraph (A) was in error.

"(3) INFORMAL HEARING.—Within 10 days of the date an order is issued under paragraph (1), the Secretary shall provide such person with an opportunity for an informal hearing, to be held within such 10 days, on the decision of the Secretary to refuse approval of an abbreviated drug application. Within 60 days of the date on which such hearing is held, the Secretary shall notify the person given such hearing whether the Secretary's refusal of approval will be continued, terminated, or otherwise modified. Such notification shall be final agency action.

"(g) SUSPENSION AUTHORITY.—

"(1) IN GENERAL.—If—

"(A) the Secretary finds—

"(i) that a person has engaged in conduct described in subparagraph (B) of subsection (f)(1) in connection with 2 or more drugs under abbreviated drug applications, or

"(ii) that a person has engaged in flagrant and repeated, material violations of good manufacturing practice or good laboratory practice in connection with the development, manufacturing, or distribution of one or more drugs approved under an abbreviated drug application during a 2-year period, and—

"(I) such violations may undermine the safety and efficacy of such drugs, and

"(II) the causes of such violations have not been corrected within a reasonable period of time following notice of such violations by the Secretary, and

"(B) such person is under an active investigation by a Federal authority in connection with a civil or criminal action involving conduct described in subparagraph (A),

the Secretary shall issue an order suspending the distribution of all drugs the development or approval of which was related to such conduct described in subparagraph (A) or suspending the distribution of all drugs approved under abbreviated drug applications of such person if the Secretary finds that such conduct may have affected the development or approval of a significant number of drugs which the Secretary is unable to identify. The Secretary shall exclude a drug from such order if the Secretary determines that such conduct was not likely to have influenced the safety or efficacy of such drug.

"(2) PUBLIC HEALTH WAIVER.—The Secretary shall, on the Secretary's own initiative or in response to a petition, waive the suspension under paragraph (1) (involving an action described in paragraph (1)(A)(i)) with respect to any drug if the Secretary finds that such waiver is necessary to protect the public health because sufficient quantities of the drug would not otherwise be available. The Secretary shall act on any petition seeking action under this paragraph within 180 days of the date the petition is submitted to the Secretary.

"(h) TERMINATION OF SUSPENSION.—The Secretary shall withdraw an order of suspension of the distribution of a drug under subsection (g) if the person with respect to whom the order was issued demonstrates in a petition to the Secretary—

"(1)(A) on the basis of an audit by the Food and Drug Administration or by experts acceptable to the Food and Drug Administration, or on the basis of other information, that the development, approval, manufacturing, and distribution of such drug is in substantial compliance with the applicable requirements of this Act, and

"(B) changes in ownership, management, or operations—

"(i) fully remedy the patterns or practices with respect to which the order was issued, and

"(ii) provide reasonable assurances that such actions will not occur in the future, or

"(2) the initial determination was in error.

The Secretary shall act on a submission of a petition under this subsection within 180 days of the date of its submission and the Secretary may consider the petition concurrently with the suspension proceeding. Any information submitted to the Secretary under this subsection does not constitute an amendment or supplement to a pending or approved abbreviated drug application.

"(i) PROCEDURE.—The Secretary may not take any action under subsection (a), (b), (c), (d)(3), (g), or (h) 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.

"(j) JUDICIAL REVIEW.—

"(1) IN GENERAL.—Except as provided in paragraph (2), any person that is the subject of an adverse decision under subsection (a), (b), (c), (d), (f), (g), or (h) 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.

"(2) EXCEPTION.—Any person that is the subject of an adverse decision under clause (iii) or (iv) of subsection (b)(2)(B) may obtain a review of such decision by the United States District Court for the District of Columbia or a district court of the United States for the district in which the person resides, by filing in such court (within 30 days following the date the person is notified of the Secretary's decision) a complaint requesting that the decision be modified or set aside. In such an action, the court shall determine the matter de novo.

"(k) CERTIFICATION.—Any application for approval of a drug product shall include—

"(1) a certification that the applicant did not and will not use in any capacity the services of any person debarred under subsection (a) or (b), in connection with such application, and

"(2) if such application is an abbreviated drug application, a list of all convictions, described in subsections (a) and (b) which occurred within the previous 5 years, of the applicant and affiliated persons responsible for the development or submission of such application.

"(l) APPLICABILITY.—

"(1) CONVICTION.—For purposes of this section, a person is considered to have been convicted of a criminal offense—

"(A) when a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending,

"(B) when a plea of guilty or nolo contendere by the person has been accepted by a Federal or State court, or

"(C) when the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement or program where judgment of conviction has been withheld.

"(2) EFFECTIVE DATES.—Subsection (a), subparagraph (A) of subsection (b)(2), and clauses (i) and (ii) of subsection (b)(2)(B) shall not apply to a conviction which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (a) or (b). Clauses (iii) and (iv) of subsection (b)(2)(B) and subsections (f) and (g) shall not apply to an act or action which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (b), (f), or (g). Clause (iv) of subsection (b)(2)(B) shall not apply to an action which occurred before June 1, 1992. Subsection (k) shall not apply to applications submitted to the Secretary before June 1, 1992.".

SEC. 3. CIVIL PENALTIES.

Chapter III, as amended by section 2, is amended by adding after section 306 the following:

"CIVIL PENALTIES

"SEC. 307. (a) IN GENERAL.—Any person that the Secretary finds— 21 USC 335b.

"(1) knowingly made or caused to be made, to any officer, employee, or agent of the Department of Health and Human Services, a false statement or misrepresentation of a material fact in connection with an abbreviated drug application,

"(2) bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services in connection with an abbreviated drug application,

"(3) destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document or other material evidence which was the property of or in the possession of the Department of Health and Human Services for the purpose of interfering with that Department's discharge of its responsibilities in connection with an abbreviated drug application,

"(4) knowingly failed to disclose, to an officer or employee of the Department of Health and Human Services, a material fact which such person had an obligation to disclose relating to any drug subject to an abbreviated drug application,

"(5) knowingly obstructed an investigation of the Department of Health and Human Services into any drug subject to an abbreviated drug application,

"(6) is a person that has an approved or pending drug product application and has knowingly—

"(A) employed or retained as a consultant or contractor, or

"(B) otherwise used in any capacity the services of,

a person who was debarred under section 306, or

"(7) is an individual debarred under section 306 and, during the period of debarment, provided services in any capacity to a person that had an approved or pending drug product application,

shall be liable to the United States for a civil penalty for each such violation in an amount not to exceed $250,000 in the case of an individual and $1,000,000 in the case of any other person.

"(b) PROCEDURE.—

"(1) IN GENERAL.—

"(A) ACTION BY THE SECRETARY.—A civil penalty under subsection (a) shall be assessed by the Secretary on a person by an order made on the record after an opportunity for an agency hearing on disputed issues of material fact and the amount of the penalty. In the course of any investigation or hearing under this subparagraph, 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.

"(B) ACTION BY THE ATTORNEY GENERAL.—In lieu of a proceeding under subparagraph (A), the Attorney General

may, upon request of the Secretary, institute a civil action to recover a civil money penalty in the amount and for any of the acts set forth in subsection (a). Such an action may be instituted separately from or in connection with any other claim, civil or criminal, initiated by the Attorney General under this Act.

"(2) AMOUNT.—In determining the amount of a civil penalty under paragraph (1), the Secretary or the court shall take into account the nature, circumstances, extent, and gravity of the act subject to penalty, the person's ability to pay, the effect on the person's ability to continue to do business, any history of prior, similar acts, and such other matters as justice may require.

"(3) LIMITATION ON ACTIONS.—No action may be initiated under this section—

"(A) with respect to any act described in subsection (a) that occurred before the date of the enactment of this Act, or

"(B) more than 6 years after the date when facts material to the act are known or reasonably should have been known by the Secretary but in no event more than 10 years after the date the act took place.

"(c) JUDICIAL REVIEW.—Any person that is the subject of an adverse decision under subsection (b)(1)(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.

"(d) RECOVERY OF PENALTIES.—The Attorney General may recover any civil penalty (plus interest at the currently prevailing rates from the date the penalty became final) assessed under subsection (b)(1)(A) in an action brought in the name of the United States. The amount of such penalty may be deducted, when the penalty has become final, from any sums then or later owing by the United States to the person against whom the penalty has been assessed. In an action brought under this subsection, the validity, amount, and appropriateness of the penalty shall not be subject to judicial review.

"(e) INFORMANTS.—The Secretary may award to any individual (other than an officer or employee of the Federal Government or a person who materially participated in any conduct described in subsection (a)) who provides information leading to the imposition of a civil penalty under this section an amount not to exceed—

"(1) $250,000, or

"(2) one-half of the penalty so imposed and collected,

whichever is less. The decision of the Secretary on such award shall not be reviewable.".

SEC. 4. AUTHORITY TO WITHDRAW APPROVAL OF ABBREVIATED DRUG APPLICATIONS.

Chapter III, as amended by sections 2 and 3, is amended by adding after section 307 the following:

"AUTHORITY TO WITHDRAW APPROVAL OF ABBREVIATED DRUG APPLICATIONS

21 USC 335c.

"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— Records.

"(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.".

21 USC 335a note.

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.

Approved May 13, 1992.

LEGISLATIVE HISTORY—H.R. 2454:

HOUSE REPORTS: No. 102-272 (Comm. on Energy and Commerce).
CONGRESSIONAL RECORD:
Vol. 137 (1991): Oct. 28, 31, considered and passed House.
Vol. 138 (1992): Apr. 10, considered and passed Senate, amended.
Apr. 28, House concurred in Senate amendments.