I

107TH CONGRESS
1ST SESSION

H. R. 3580

To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 20, 2001

Mr. GREENWOOD (for himself, Ms. ESHOO, Mr. UPTON, Mr. PALLONE, Mr. DEUTSCH, Mr. TOWNS, Mr. BRYANT, and Mr. BARTON of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.

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

SECTION 1. SHORT TITLE AND REFERENCE TO ACT.

(a) SHORT TITLE.—This Act may be cited as the ''Medical Device Amendments of 2001''.

(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.

SEC. 2. DESIGNATION AND REGULATION OF COMBINATION AND SINGLE ENTITY PRODUCTS.

Section 503(g) is amended by redesignating paragraph (4) as (5) and inserting after paragraph (3) the following paragraph:

''(4)(A) Within six months after the date of the enactment of the Medical Device Amendments of 2001, the Secretary shall establish within the Office of the Commissioner of Food and Drugs an office to be known as the Office of Combination Products and Product Jurisdiction (referred to in this paragraph as the 'Office'), which shall be responsible for designating the Center with primary or exclusive responsibility for the premarket and postmarket regulation of drugs, devices and biological products. The Office shall be managed by a person with appropriate scientific expertise and shall oversee the regulation of such products to ensure timely and effective premarket reviews, and predictable and consistent postmarket requirements.

''(B) The Office shall assign for regulation all products subject to this Act based on the primary mode of action. The component within the Food and Drug Administration with primary or exclusive responsibility for regulating a product shall be determined according to the re-

quirements of subparagraphs (A) through (C) of paragraph (1). All products which meet the definition of device or drug within the meaning of section 201, or biological product as defined under section 351(i) of the Public Health Service Act shall be regulated only by the persons within the Food and Drug Administration who are primarily charged with the regulation of such products. In vitro reagents, as that term is used in section 201(h), shall be regulated by those persons within the Food and Drug Administration primarily charged with reviewing devices.

''(C)(i) The assignment of a product to a component of the Food and Drug Administration shall be for purposes of premarket and postmarket regulation.

''(ii) After such an assignment, all persons associated with shared premarket reviews, including reviews with input from a consulting agency component or reviews in which more than one premarket clearance is necessary, shall be responsible to and under the supervision of the Office for purposes of such reviews.

''(iii) Any disputes regarding the timeliness or substance of such reviews may be presented to the Office for resolution. The decision of the Office shall be subject exclusively to review by the Commissioner of Food and Drugs and such review shall not be delegated.

''(iv) The postmarket regulatory requirements for combination products shall be under the same type of product authorities as those relied upon to approve, clear, or license such products, unless two types of product authorities are necessary to permit the commercial distribution of a combination product. When more than one type of product authority is necessary to permit the commercial distribution of a combination product, each component of such product shall be subject to the postmarket requirements of the regulatory authority relied upon to permit the commercial distribution of each such component comprising the combination product.

''(D) The Office shall not be bound by any existing agreement, guidance or agency practice recommending assignment or assigning any device, drug, biological product, or combination product to any component of the Food and Drug Administration, unless the product is assigned to the agency component primarily charged with regulating each such product. The Office shall review each agency agreement, guidance or practice and determine whether they are consistent with the requirements of this subsection. As part of the review process, the Office shall publish for comment each such agreement, guidance or statement of practices. After receipt and analysis of comments, the Office shall determine whether to adopt, and to what extent,

any of the agency's existing agreements, guidance documents or practices.

''(E) One year after the date of the enactment of the Medical Device Amendments of 2001 and for each year thereafter, the Secretary shall report to the appropriate committees of Congress the accomplishments, including the impact on the efficiency and quality of product regulation, of the Office. Among other things, such report shall describe the activities of the Office, identify the number of premarket reviews involving more than one review component of the Food and Drug Administration, discuss the timeliness and consistency of combination product premarket reviews, and demonstrate the Office's progress or lack of progress in ensuring timely and effective reviews of such products.''.

SEC. 3. STRENGTHENING THIRD PARTY REVIEW OF PREMARKET NOTIFICATION.

Section 523 (21 U.S.C. 360m) is amended—

(1) in subsection (a), by striking paragraph (3) and inserting the following:

''(3) ELIGIBLE DEVICES.—

''(A) IN GENERAL.—Each type of device subject to the requirement of premarket notification under section 510(k) shall be eligible for review by persons accredited under subsection

(a), unless the Secretary after notice and comment promulgates a regulation excluding a type of device or specific devices within a type from review by accredited persons under this section.

''(B) EXCEPTION.—Any type of device or specific device that was eligible for premarket notification review by persons accredited under this section six months prior to the date of the enactment of the Medical Device Amendments of 2001 shall continue to be eligible for such review, unless the Secretary determines that premarket notification by the Secretary is necessary to assure reasonable assurance of safety and effectiveness. After making this determination, the Secretary shall promulgate a regulation after notice and comment rulemaking to exclude such a type of device or specific device from review under this section.''; and

(2) by striking subsection (c).

SEC. 4. AUGMENTING EXPERTISE.

(a) CENTER FOR DEVICES FELLOWSHIP PROGRAM.—The Federal Food, Drug and Cosmetic Act is amended by adding at the end the following:

"SEC. 908. DEVICES FELLOWSHIP PROGRAM.

''(a) IN GENERAL.—Without regard to the provisions of title 5, United States Code, governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, the Commissioner of Food and Drugs may establish a fellowship program within the component of the agency responsible for regulating devices for the purpose of augmenting and enriching the scientific expertise of that agency component. Any person receiving such a fellowship shall be available to participate in any matter in which the participation of such person would not create a conflict of interest, and shall be subject to the same requirements applicable to full time employees regarding the protection and use of trade secret and confidential commercial or financial information.

''(b) ELIGIBILITY.—Any qualified person not an employee of the Federal or a state government may be eligible for the fellowship identified in subsection (a). The granting of a fellowship to the candidate shall be the result of the unanimous agreement of a group of five (5) senior officials designated by the Commissioner, including at least three from the component of the Food and Drug Administration responsible for regulating devices. These officials shall evaluate the technical background and achieve-

ments of each candidate, the significance of the candidate's expertise to the agency's needs, and the candidate's character and likely contributions to the agency.''.

(b) OUTSIDE EXPERT REVIEWS.—Section 515(c) (21 U.S.C. 360e(c) is amended by adding at the end the following:

''(3)(A) Either at the initiation of the Secretary or the applicant, any person who is (i) not an employee of the Federal or a state government, and (ii) an expert in a subject matter germane to an application under paragraph (1) may be selected by the Secretary to review all or part of a premarket approval application submitted under this section, after considering recommendations of experts from applicants, if any. The decision to use such an expert shall be made by agreement between the Secretary and the applicant, and the applicant may choose not to retain an expert for any reason, including the cost of the expert's compensation. The compensation for such an expert review shall be determined by the expert and the applicant.

''(B) The Secretary shall prescribe the terms of the review, including the amount of time allocated to such experts to submit to the Secretary and the applicant a report and recommendation evaluating that portion of the application the Secretary designated for review.

''(C) The Secretary shall promptly consider the recommendation of an expert reviewer and provide a detailed written explanation of any portion of the recommendation with which the Secretary disagrees.''.

(c) INSPECTIONS BY ACCREDITED PERSONS.—Section 704 (21 U.S.C. 374) is amended by adding at the end the following:

''(g)(1) Not later than one year after the date of the enactment of the Medical Device Amendments of 2001, the Secretary shall accredit persons to conduct inspections authorized under subsection (a) at facilities designated as eligible for inspections by accredited persons who are not employees of the Federal or a state government. The owner or operator of an eligible facility shall have the option to use an accredited person in lieu of officers or employees designated by the Secretary to conduct such inspections, including inspections to satisfy the good manufacturing practice requirements of section 515.

''(2) Not later than 180 days after the date of the enactment of the Medical Device Amendments of 2001, the Secretary shall publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1). Thereafter, the Secretary shall respond to a request for accreditation within 60 days of the receipt of a request. The ac-

creditation shall state that such person is accredited to conduct device facility inspections under subsection (a).

''(3) An accredited person shall, at a minimum, meet the following requirements:

''(A) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under the Act and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

''(B) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

''(C) Such person shall not engage in the design, manufacture, promotion, or sale of articles regulated under the Act.

''(D) The operations of such person shall be in accordance with generally accepted professional and ethical business practices and such persons shall agree in writing that as a minimum it will—

''(i) certify that reported information accurately reflects data reviewed;

''(ii) limit work to that for which competence and capacity are available;

''(iii) treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information; and

''(iv) protect against the use, in carrying out paragraph (1), of any officer or employee of the accredited person who has a financial conflict of interest regarding any product regulated under the Act, and annually make available to the public disclosures of the extent to which the accredited person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

''(4) The Secretary shall publish a list of accredited persons to conduct inspections under subsection (a) on the Food and Drug Administration's web page. Those who elect to employ an accredited person shall select such a person from the list posted by the Secretary. Such list shall be periodically updated to ensure that the identity of each accredited person is known to the public. The updating of such list shall be no later than one month after the accreditation of a person under this subsection.

''(5) To ensure that persons accredited under this subsection continue to meet the standards of accredita-

tion, the Secretary shall (i) audit the performance of such persons on a periodic basis; and (ii) take such additional measures as the Secretary deems appropriate, including the withdrawal of accreditation when persons accredited under this subsection fail to maintain compliance with the accreditation criteria established by the Secretary.

''(6) Device facilities in which the Secretary classified the results of the facility's most recent inspection under subsection (a) as ''no action indicated'' or ''voluntary action indicated'', or those facilities in which after the most recent inspection, the Secretary determines that satisfactory compliance with section 520(f) supports the approval of a device under section 515, shall be eligible for inspections by persons accredited by the Secretary under paragraph (2). The Federal Food and Drug Administration shall not inspect an eligible facility unless—

''(A) the facility is not inspected by an accredited person for the 2 year period following the date of a ''no action indicated'' or ''voluntary action indicated'' finding by the Secretary;

''(B) after an inspection by the Secretary, or after the Secretary's review of a report of an inspection from an accredited person, the Secretary determines in writing that a facility is no longer eligible for inspections by accredited persons; or

''(C) the Secretary has good cause for conducting an inspection.

''(7) Persons accredited under this subsection to conduct inspections shall record in writing their inspection observations and shall present to the device facility's designated representative and discuss each observation. Additionally, such accredited person shall prepare an inspection report in a form and manner consistent with such reports prepared by employees and officials designated by the Secretary to conduct inspections under subsection (a). At a minimum, such reports shall identify the persons responsible for good manufacturing practice compliance at an inspected establishment, discuss in detail each observation identified by the accredited person, identify other matters that relate or may influence compliance with the Act, and discuss any recommendations made during the inspection or at the inspection's closing meeting. The report of the inspection shall be sent to the Secretary and the designated representative of an inspected facility at the same time, but under no circumstances later than 3 weeks after the last day of the inspection.

''(8) Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited

person, and shall be paid by the person who engages such services.''.

SEC. 5. SPECIAL PROCESS FOR BREAKTHROUGH TECHNOLOGIES.

Section 515(d)(5) (21 U.S.C. 360e(d)(5)) is amended—

(1) by redesignating subparagraphs (A) through (D) as clauses (i) through (iv), respectively;

(2) by inserting ''(A)'' after ''(5)''; and

(3) by adding at the end the following subparagraph:

''(B)(i) In order to provide patients with the benefits of devices referenced in subparagraph (A) in the treatment and diagnosis of serious diseases or conditions, the Secretary shall within six months after the date of the enactment of the Medical Device Amendments of 2001 promulgate a regulation setting forth a process to designate devices as 'priority devices'. Such regulation shall include, among other things, requirements for (I) the specification of the contents of submissions requesting priority status; (II) a meeting to fully discuss the submission; (III) a written response no later than 30 days after the receipt of a submission granting or denying priority status; and (IV) an administrative appeal before the director or a deputy director of the Office of Device Evaluation, or any suc-

cessor unit, within 10 days of a written determination denying a device a priority designation. A request for a priority device designation may be made at any time, including times prior to the investigation of a device.

''(ii) A device which the Secretary designates as a priority device shall be subject to a review period of no longer than 120 days following the designation determination, at which time the Secretary shall approve or deny the application submitted to support approval of the device. The determination to approve or deny a premarket application for a priority device shall take into consideration the following in determining a reasonable assurance of device safety and effectiveness:

''(I) Whether the likely risk to expected health of patients is less from using a priority device than the risk of not having the device available to treat or diagnose a disease or condition.

''(II) Whether the amount of benefit from a priority device would exceed the benefit for an individual patient relative to no treatment or diagnosis, or to alternative means of treatment or diagnosis.

''(III) A comparison of risk to benefit as described in subclauses (I) and (II), respectively.

''(iii)(I) The Secretary, in the context of a meeting under section 520(g)(7), shall agree, when appropriate, to

review data at an interim point in a clinical trial for purposes of determining reasonable assurance of device safety and effectiveness. Such interim reviews shall be subject to the conditions that the Secretary deems appropriate, including that the approval will become null and void if it is demonstrated at a consultation with the Director of the Office of Device Evaluation (or any successor unit) that the conclusions based on data from the completed clinical trial are inconsistent with those from the interim analysis and such conclusions would have resulted in denial of the application.

''(II) The Secretary shall rely on appropriate endpoints, including surrogate endpoints, when evaluating an application for a priority device to determine whether there exists a reasonable assurance of safety and effectiveness.

''(iv) To ensure a complete, fully informed and timely review of applications for priority devices, the Secretary shall include in the regulation referenced in subparagraph (B)(i) a provision requiring persons responsible for reviewing applications for such devices to meet with applicants to jointly consider such applications. Such meetings shall commence not later than the ninetieth day after receipt of an application that satisfies the criteria for completeness set forth in subsection (c). Such meetings shall pro-

vide adequate time for applicants and government employees to review an entire submission to ensure that applicants can quickly and effectively supplement applications for priority devices.''.

SEC. 6. INCREASING REPORTING EFFECTIVENESS.

Section 519(a)(1) (21 U.S.C. 360i(a)(1)) is amended by inserting after and below subparagraph (B) the following:

''except that such reports shall only be required when the Secretary identifies a type of device in the Federal Register for which the Secretary intends to require malfunction reporting, which malfunction reporting shall be in effect after a 60 day comment period and the Secretary's Federal Register announcement that a type of device is subject to such reporting, and which malfunction reporting shall be on a quarterly basis, and shall be limited to information describing the device and the event, the date and location of the event, and the identity of the person at the facility or place where the event occurred upon whom the reporter relied for information;''.

SEC. 7. INDICATIONS FOR USE.

(a) PREMARKET NOTIFICATION PROPOSED INTENDED USE.—Section 513(i)(1)(E) (21 U.S.C. 360c(i)(1)(E)) is amended by striking clause (iv).

(b) PREMARKET APPROVAL PROPOSED CONDITIONS OF USE.—Section 515(d)(1)(A) (21 U.S.C. 360e(d)(1)(A)) is amended by adding at the end the following: ''Whenever the Secretary determines that proposed labeling is false or misleading, the Secretary shall, no later than 150 days after receipt of an application filed under subsection (c), notify the applicant in writing of the basis for such a determination.''.

(c) SUPPLEMENTS FOR CERTAIN CONDITIONS OF USE.—Section 515(d)(6) (21 U.S.C. 360e(d)(6)) is amended by adding at the end the following subparagraph:

''(C)(i) Subject to clause (ii), in reviewing any supplement to an approved application, which is submitted to obtain the additional specification of a subpopulation under an approved condition of use, the Secretary shall approve such supplement without additional clinical data when—

''(I) the underlying conditions of use of the device are otherwise unchanged from that approved by the Secretary; and

''(II) preclinical and clinical data exist in the approved application applicable to the safe and effective use of the device in the specified subpopulation, or a bona fide peer review journal article reporting clinical experience with the device in the subpopula-

tion demonstrates that there is reasonable assurance of the device's safety and effectiveness.

''(ii) In evaluating an indication for such a patient subpopulation, the Secretary may require, when necessary, the submission of clinical data to determine whether there is a reasonable assurance of safety and effectiveness.''.

SEC. 8. IMPROVING COLLABORATION.

(a) LEAST BURDENSOME DETERMINATIONS.—Section 513(a)(3)(D) (21 U.S.C. 360c(a)(3)(D)) is amended—

(1) in clause (i), by inserting ''within 20 days of such a request'' after ''section 515, shall''; and

(2) by striking clause (ii) and inserting the following:

''(ii) Any clinical data and other valid scientific evidence, specified in writing by the Secretary to demonstrate reasonable assurance of device effectiveness shall represent a determination by the Secretary that such evidence is the least burdensome information necessary to satisfy a finding of effectiveness for purposes of approving a device under subsection 515(d).''.

(b) INVESTIGATIONAL PLAN AGREEMENT MEETINGS.—Section 520(g)(7) (21 U.S.C. 360j(g)(7)) is amended—

(1) in subparagraph (A)—

(A) by striking the first sentence and inserting the following: ''In the case of a person intending to investigate the safety and effectiveness or substantial equivalence of a device, and such investigation includes the undertaking of a clinical trial, the Secretary shall ensure that such person has an opportunity, prior to submitting an application under section 515 or a premarket notification under section 510(k) to the Secretary or an institutional review committee, to submit to the Secretary an investigational plan (including a clinical protocol) for review.''; and

(B) by striking the last sentence and inserting the following: ''The written request shall include a detailed description of the device, including the device's proposed indications or conditions of use, and a proposed investigational plan or any part of such plan to which the submitter seeks review and agreement.''; and

(2) in subparagraph (B), in the matter preceding clause (i), by inserting after ''applicant shall'' the following: ''reflect the least burdensome information necessary to support an approval under section

515 or a substantial equivalence determination under section 513(f)(1), and shall''.

(c) IMPROVING INTERIM PMA REVIEW MEETINGS.—Section 515(d)(3)(A) (21 U.S.C. 360e(d)(3)(A)) is amended—

(1) in clause (i), by inserting at the end the following: ''The term application, as used in this paragraph, shall include any submission made under this section, or regulations implementing this section, which is subject to a 180 day review period.''; and

(2) in clause (ii), by inserting at the end the following: ''The written identification of deficiencies and the specific information that is required to correct such deficiencies shall be provided to the applicant no later than 10 days prior to the meeting.''.

SEC. 9. GUIDANCE.

(a) IN GENERAL.—Section 701(h)(1)(C) (21 U.S.C. 371(h)(1)(C)) is amended—

(1) by inserting ''(i)'' after ''(C)''; and

(2) by adding at the end the following:

''(ii)(I) After a request for participation from individuals or groups not employed or associated with Federal or State governments to participate in the development of specific guidance or policy documents, the Secretary shall meet with such individuals or groups to obtain input into

the guidance development process when such persons or groups have expertise germane to the subject matter of potential guidance or policy documents and, in the opinion of the Secretary, such persons or groups can provide information that will enhance the Secretary's public health assessment of the impact of a potential guidance or policy document.

''(II) Any request under subclause (I) shall identify the expertise, and relevance of such expertise, to the development of a guidance or policy document, or the information that would justify a meeting because of the expected benefit to the public health resulting from such information.

''(III) Each meeting with an individual or group under subclause (I) shall be promptly identified through publication of the Secretary's calendar.''.

SEC. 10. MODULAR REVIEW.

Section 515(c) (21 U.S.C. 360e(c)), as amended by section 4(b) of this Act, is further amended by adding at the end the following:

''(4)(A) Prior to the submission of an application under this subsection, the Secretary shall accept and review portions of such applications that applicants and the Secretary agree are complete and ready for review.

''(B) Each portion of a submission reviewed under subparagraph (A) and found acceptable by the Secretary shall not be further reviewed after receipt of an application that satisfies the requirements of paragraph (1), unless new information provides the Secretary cause to review such accepted portion.

''(C) Whenever the Secretary determines that a portion of a submission under subparagraph (A) is unacceptable, the Secretary shall specifically identify, in writing, the deficiency of such portion and describe in detail the means by which it may be made acceptable.''.

SEC. 11. REGISTRATION.

(a) IN GENERAL.—Section 510(b) (21 U.S.C. 360(b)) is amended to read as follows:

''(b)(1) Every second year after initially registering, every person who owns or operates any establishment in any State, territory, or foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices shall register with the Secretary his name, place of business, and such establishment.

''(2) Every person who registers under this section shall update such person's registration information within 30 days of any change or event, when information about

such change or event is required by regulations promulgated by the Secretary.

''(3) Initial registrations and registration updates shall be submitted to the Secretary by electronic means, unless the Secretary grants a request for waiver of this requirement because use of electronic communications is not reasonable for the regulated person requesting such waiver.''.

(b) CONFORMING AMENDMENT.—Section 510(d) (21 U.S.C. 360(d)) is amended by striking ''immediately''.

SEC. 12. ELECTRONIC LABELING.

Section 201(m) (21 U.S.C. 321(m)) is amended by adding at the end the following: ''For purposes of providing adequate directions for use, labeling may also include written, printed, or graphic matter which is displayed by electronic means and is intended as labeling by the person responsible for labeling an article.''.

○