

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE AND REFERENCE TO ACT.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medical Device Amendments of 2001”.

6 (b) REFERENCE.—Whenever in this Act an amend-
7 ment or repeal is expressed in terms of an amendment
8 to, or repeal of, a section or other provision, the reference

1 shall be considered to be made to a section or other provi-
2 sion of the Federal Food, Drug, and Cosmetic Act.

3 **SEC. 2. DESIGNATION AND REGULATION OF COMBINATION**
4 **AND SINGLE ENTITY PRODUCTS.**

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

8 “(4)(A) Within six months after the date of the en-
9 actment of the Medical Device Amendments of 2001, the
10 Secretary shall establish within the Office of the Commis-
11 sioner of Food and Drugs an office to be known as the
12 Office of Combination Products and Product Jurisdiction
13 (referred to in this paragraph as the ‘Office’), which shall
14 be responsible for designating the Center with primary or
15 exclusive responsibility for the premarket and postmarket
16 regulation of drugs, devices and biological products. The
17 Office shall be managed by a person with appropriate sci-
18 entific expertise and shall oversee the regulation of such
19 products to ensure timely and effective premarket reviews,
20 and predictable and consistent postmarket requirements.

21 “(B) The Office shall assign for regulation all prod-
22 ucts subject to this Act based on the primary mode of ac-
23 tion. The component within the Food and Drug Adminis-
24 tration with primary or exclusive responsibility for regu-
25 lating a product shall be determined according to the re-

1 requirements of subparagraphs (A) through (C) of para-
2 graph (1). All products which meet the definition of device
3 or drug within the meaning of section 201, or biological
4 product as defined under section 351(i) of the Public
5 Health Service Act shall be regulated only by the persons
6 within the Food and Drug Administration who are pri-
7 marily charged with the regulation of such products. In
8 vitro reagents, as that term is used in section 201(h), shall
9 be regulated by those persons within the Food and Drug
10 Administration primarily charged with reviewing devices.

11 “(C)(i) The assignment of a product to a component
12 of the Food and Drug Administration shall be for pur-
13 poses of premarket and postmarket regulation.

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

20 “(iii) Any disputes regarding the timeliness or sub-
21 stance of such reviews may be presented to the Office for
22 resolution. The decision of the Office shall be subject ex-
23 clusively to review by the Commissioner of Food and
24 Drugs and such review shall not be delegated.

1 “(iv) The postmarket regulatory requirements for
2 combination products shall be under the same type of
3 product authorities as those relied upon to approve, clear,
4 or license such products, unless two types of product au-
5 thorities are necessary to permit the commercial distribu-
6 tion of a combination product. When more than one type
7 of product authority is necessary to permit the commercial
8 distribution of a combination product, each component of
9 such product shall be subject to the postmarket require-
10 ments of the regulatory authority relied upon to permit
11 the commercial distribution of each such component com-
12 prising the combination product.

13 “(D) The Office shall not be bound by any existing
14 agreement, guidance or agency practice recommending as-
15 signment or assigning any device, drug, biological product,
16 or combination product to any component of the Food and
17 Drug Administration, unless the product is assigned to the
18 agency component primarily charged with regulating each
19 such product. The Office shall review each agency agree-
20 ment, guidance or practice and determine whether they
21 are consistent with the requirements of this subsection.
22 As part of the review process, the Office shall publish for
23 comment each such agreement, guidance or statement of
24 practices. After receipt and analysis of comments, the Of-
25 fice shall determine whether to adopt, and to what extent,

1 any of the agency’s existing agreements, guidance docu-
2 ments or practices.

3 “(E) One year after the date of the enactment of the
4 Medical Device Amendments of 2001 and for each year
5 thereafter, the Secretary shall report to the appropriate
6 committees of Congress the accomplishments, including
7 the impact on the efficiency and quality of product regula-
8 tion, of the Office. Among other things, such report shall
9 describe the activities of the Office, identify the number
10 of premarket reviews involving more than one review com-
11 ponent of the Food and Drug Administration, discuss the
12 timeliness and consistency of combination product pre-
13 market reviews, and demonstrate the Office’s progress or
14 lack of progress in ensuring timely and effective reviews
15 of such products.”.

16 **SEC. 3. STRENGTHENING THIRD PARTY REVIEW OF PRE-**
17 **MARKET NOTIFICATION.**

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

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

21 “(3) ELIGIBLE DEVICES.—

22 “(A) IN GENERAL.—Each type of device
23 subject to the requirement of premarket notifi-
24 cation under section 510(k) shall be eligible for
25 review by persons accredited under subsection

1 (a), unless the Secretary after notice and com-
2 ment promulgates a regulation excluding a type
3 of device or specific devices within a type from
4 review by accredited persons under this section.

5 “(B) EXCEPTION.—Any type of device or
6 specific device that was eligible for premarket
7 notification review by persons accredited under
8 this section six months prior to the date of the
9 enactment of the Medical Device Amendments
10 of 2001 shall continue to be eligible for such re-
11 view, unless the Secretary determines that pre-
12 market notification by the Secretary is nec-
13 essary to assure reasonable assurance of safety
14 and effectiveness. After making this determina-
15 tion, the Secretary shall promulgate a regula-
16 tion after notice and comment rulemaking to
17 exclude such a type of device or specific device
18 from review under this section.”; and

19 (2) by striking subsection (c).

20 **SEC. 4. AUGMENTING EXPERTISE.**

21 (a) CENTER FOR DEVICES FELLOWSHIP PRO-
22 GRAM.—The Federal Food, Drug and Cosmetic Act is
23 amended by adding at the end the following:

1 **“SEC. 908. DEVICES FELLOWSHIP PROGRAM.**

2 “(a) IN GENERAL.—Without regard to the provisions
3 of title 5, United States Code, governing appointments in
4 the competitive service and without regard to the provi-
5 sions of chapter 51 and subchapter III of chapter 53 of
6 such title relating to classification and General Schedule
7 pay rates, the Commissioner of Food and Drugs may es-
8 tablish a fellowship program within the component of the
9 agency responsible for regulating devices for the purpose
10 of augmenting and enriching the scientific expertise of
11 that agency component. Any person receiving such a fel-
12 lowship shall be available to participate in any matter in
13 which the participation of such person would not create
14 a conflict of interest, and shall be subject to the same re-
15 quirements applicable to full time employees regarding the
16 protection and use of trade secret and confidential com-
17 mercial or financial information.

18 “(b) ELIGIBILITY.—Any qualified person not an em-
19 ployee of the Federal or a state government may be eligi-
20 ble for the fellowship identified in subsection (a). The
21 granting of a fellowship to the candidate shall be the result
22 of the unanimous agreement of a group of five (5) senior
23 officials designated by the Commissioner, including at
24 least three from the component of the Food and Drug Ad-
25 ministration responsible for regulating devices. These offi-
26 cials shall evaluate the technical background and achieve-

1 ments of each candidate, the significance of the can-
2 didate’s expertise to the agency’s needs, and the can-
3 didate’s character and likely contributions to the agency.”.

4 (b) OUTSIDE EXPERT REVIEWS.—Section 515(c) (21
5 U.S.C. 360e(c) is amended by adding at the end the fol-
6 lowing:

7 “(3)(A) Either at the initiation of the Secretary or
8 the applicant, any person who is (i) not an employee of
9 the Federal or a state government, and (ii) an expert in
10 a subject matter germane to an application under para-
11 graph (1) may be selected by the Secretary to review all
12 or part of a premarket approval application submitted
13 under this section, after considering recommendations of
14 experts from applicants, if any. The decision to use such
15 an expert shall be made by agreement between the Sec-
16 retary and the applicant, and the applicant may choose
17 not to retain an expert for any reason, including the cost
18 of the expert’s compensation. The compensation for such
19 an expert review shall be determined by the expert and
20 the applicant.

21 “(B) The Secretary shall prescribe the terms of the
22 review, including the amount of time allocated to such ex-
23 perts to submit to the Secretary and the applicant a report
24 and recommendation evaluating that portion of the appli-
25 cation the Secretary designated for review.

1 “(C) The Secretary shall promptly consider the rec-
2 ommendation of an expert reviewer and provide a detailed
3 written explanation of any portion of the recommendation
4 with which the Secretary disagrees.”.

5 (c) INSPECTIONS BY ACCREDITED PERSONS.—Sec-
6 tion 704 (21 U.S.C. 374) is amended by adding at the
7 end the following:

8 “(g)(1) Not later than one year after the date of the
9 enactment of the Medical Device Amendments of 2001,
10 the Secretary shall accredit persons to conduct inspections
11 authorized under subsection (a) at facilities designated as
12 eligible for inspections by accredited persons who are not
13 employees of the Federal or a state government. The
14 owner or operator of an eligible facility shall have the op-
15 tion to use an accredited person in lieu of officers or em-
16 ployees designated by the Secretary to conduct such in-
17 spections, including inspections to satisfy the good manu-
18 facturing practice requirements of section 515.

19 “(2) Not later than 180 days after the date of the
20 enactment of the Medical Device Amendments of 2001,
21 the Secretary shall publish in the Federal Register criteria
22 to accredit or deny accreditation to persons who request
23 to perform the duties specified in paragraph (1). There-
24 after, the Secretary shall respond to a request for accredi-
25 tation within 60 days of the receipt of a request. The ac-

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

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

5 “(A) Such person shall be an independent orga-
6 nization which is not owned or controlled by a man-
7 ufacturer, supplier, or vendor of articles regulated
8 under the Act and which has no organizational, ma-
9 terial, or financial affiliation with such a manufac-
10 turer, supplier, or vendor.

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

14 “(C) Such person shall not engage in the de-
15 sign, manufacture, promotion, or sale of articles reg-
16 ulated under the Act.

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

21 “(i) certify that reported information accu-
22 rately reflects data reviewed;

23 “(ii) limit work to that for which com-
24 petence and capacity are available;

1 “(iii) treat information received, records,
2 reports, and recommendations as confidential
3 commercial or financial information or trade se-
4 cret information; and

5 “(iv) protect against the use, in carrying
6 out paragraph (1), of any officer or employee of
7 the accredited person who has a financial con-
8 flict of interest regarding any product regulated
9 under the Act, and annually make available to
10 the public disclosures of the extent to which the
11 accredited person, and the officers and employ-
12 ees of the person, have maintained compliance
13 with requirements under this clause relating to
14 financial conflicts of interest.

15 “(4) The Secretary shall publish a list of accredited
16 persons to conduct inspections under subsection (a) on the
17 Food and Drug Administration’s web page. Those who
18 elect to employ an accredited person shall select such a
19 person from the list posted by the Secretary. Such list
20 shall be periodically updated to ensure that the identity
21 of each accredited person is known to the public. The up-
22 dating of such list shall be no later than one month after
23 the accreditation of a person under this subsection.

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

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

7 “(6) Device facilities in which the Secretary classified
8 the results of the facility’s most recent inspection under
9 subsection (a) as “no action indicated” or “voluntary ac-
10 tion indicated”, or those facilities in which after the most
11 recent inspection, the Secretary determines that satisfac-
12 tory compliance with section 520(f) supports the approval
13 of a device under section 515, shall be eligible for inspec-
14 tions by persons accredited by the Secretary under para-
15 graph (2). The Federal Food and Drug Administration
16 shall not inspect an eligible facility unless—

17 “(A) the facility is not inspected by an accred-
18 ited person for the 2 year period following the date
19 of a “no action indicated” or “voluntary action indi-
20 cated” finding by the Secretary;

21 “(B) after an inspection by the Secretary, or
22 after the Secretary’s review of a report of an inspec-
23 tion from an accredited person, the Secretary deter-
24 mines in writing that a facility is no longer eligible
25 for inspections by accredited persons; or

1 “(C) the Secretary has good cause for con-
2 ducting an inspection.

3 “(7) Persons accredited under this subsection to con-
4 duct inspections shall record in writing their inspection ob-
5 servations and shall present to the device facility’s des-
6 ignated representative and discuss each observation. Addi-
7 tionally, such accredited person shall prepare an inspec-
8 tion report in a form and manner consistent with such
9 reports prepared by employees and officials designated by
10 the Secretary to conduct inspections under subsection (a).
11 At a minimum, such reports shall identify the persons re-
12 sponsible for good manufacturing practice compliance at
13 an inspected establishment, discuss in detail each observa-
14 tion identified by the accredited person, identify other
15 matters that relate or may influence compliance with the
16 Act, and discuss any recommendations made during the
17 inspection or at the inspection’s closing meeting. The re-
18 port of the inspection shall be sent to the Secretary and
19 the designated representative of an inspected facility at
20 the same time, but under no circumstances later than 3
21 weeks after the last day of the inspection.

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

1 person, and shall be paid by the person who engages such
2 services.”.

3 **SEC. 5. SPECIAL PROCESS FOR BREAKTHROUGH TECH-**
4 **NOLOGIES.**

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

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

9 (2) by inserting “(A)” after “(5)”; and

10 (3) by adding at the end the following subpara-
11 graph:

12 “(B)(i) In order to provide patients with the benefits
13 of devices referenced in subparagraph (A) in the treatment
14 and diagnosis of serious diseases or conditions, the Sec-
15 retary shall within six months after the date of the enact-
16 ment of the Medical Device Amendments of 2001 promul-
17 gate a regulation setting forth a process to designate de-
18 vices as ‘priority devices’. Such regulation shall include,
19 among other things, requirements for (I) the specification
20 of the contents of submissions requesting priority status;
21 (II) a meeting to fully discuss the submission; (III) a writ-
22 ten response no later than 30 days after the receipt of
23 a submission granting or denying priority status; and (IV)
24 an administrative appeal before the director or a deputy
25 director of the Office of Device Evaluation, or any suc-

1 cessor unit, within 10 days of a written determination de-
2 nying a device a priority designation. A request for a pri-
3 ority device designation may be made at any time, includ-
4 ing times prior to the investigation of a device.

5 “(ii) A device which the Secretary designates as a pri-
6 ority device shall be subject to a review period of no longer
7 than 120 days following the designation determination, at
8 which time the Secretary shall approve or deny the appli-
9 cation submitted to support approval of the device. The
10 determination to approve or deny a premarket application
11 for a priority device shall take into consideration the fol-
12 lowing in determining a reasonable assurance of device
13 safety and effectiveness:

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

18 “(II) Whether the amount of benefit from a pri-
19 ority device would exceed the benefit for an indi-
20 vidual patient relative to no treatment or diagnosis,
21 or to alternative means of treatment or diagnosis.

22 “(III) A comparison of risk to benefit as de-
23 scribed in subclauses (I) and (II), respectively.

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

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

12 “(II) The Secretary shall rely on appropriate
13 endpoints, including surrogate endpoints, when evaluating
14 an application for a priority device to determine whether
15 there exists a reasonable assurance of safety and effective-
16 ness.

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

1 vide adequate time for applicants and government employ-
2 ees to review an entire submission to ensure that appli-
3 cants can quickly and effectively supplement applications
4 for priority devices.”.

5 **SEC. 6. INCREASING REPORTING EFFECTIVENESS.**

6 Section 519(a)(1) (21 U.S.C. 360i(a)(1)) is amended
7 by inserting after and below subparagraph (B) the fol-
8 lowing:

9 “except that such reports shall only be required
10 when the Secretary identifies a type of device in the
11 Federal Register for which the Secretary intends to
12 require malfunction reporting, which malfunction re-
13 porting shall be in effect after a 60 day comment pe-
14 riod and the Secretary’s Federal Register announce-
15 ment that a type of device is subject to such report-
16 ing, and which malfunction reporting shall be on a
17 quarterly basis, and shall be limited to information
18 describing the device and the event, the date and lo-
19 cation of the event, and the identity of the person
20 at the facility or place where the event occurred
21 upon whom the reporter relied for information;”.

22 **SEC. 7. INDICATIONS FOR USE.**

23 (a) **PREMARKET NOTIFICATION PROPOSED IN-**
24 **TENDED USE.**—Section 513(i)(1)(E) (21 U.S.C.
25 360c(i)(1)(E)) is amended by striking clause (iv).

1 (b) PREMARKET APPROVAL PROPOSED CONDITIONS
2 OF USE.—Section 515(d)(1)(A) (21 U.S.C.
3 360e(d)(1)(A)) is amended by adding at the end the fol-
4 lowing: “Whenever the Secretary determines that pro-
5 posed labeling is false or misleading, the Secretary shall,
6 no later than 150 days after receipt of an application filed
7 under subsection (c), notify the applicant in writing of the
8 basis for such a determination.”.

9 (c) SUPPLEMENTS FOR CERTAIN CONDITIONS OF
10 USE.—Section 515(d)(6) (21 U.S.C. 360e(d)(6)) is
11 amended by adding at the end the following subparagraph:
12 “(C)(i) Subject to clause (ii), in reviewing any supple-
13 ment to an approved application, which is submitted to
14 obtain the additional specification of a subpopulation
15 under an approved condition of use, the Secretary shall
16 approve such supplement without additional clinical data
17 when—

18 “(I) the underlying conditions of use of the de-
19 vice are otherwise unchanged from that approved by
20 the Secretary; and

21 “(II) preclinical and clinical data exist in the
22 approved application applicable to the safe and effec-
23 tive use of the device in the specified subpopulation,
24 or a bona fide peer review journal article reporting
25 clinical experience with the device in the subpopula-

1 tion demonstrates that there is reasonable assurance
2 of the device’s safety and effectiveness.

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

7 **SEC. 8. IMPROVING COLLABORATION.**

8 (a) **LEAST BURDENSOME DETERMINATIONS.**—Sec-
9 tion 513(a)(3)(D) (21 U.S.C. 360c(a)(3)(D)) is
10 amended—

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

13 (2) by striking clause (ii) and inserting the fol-
14 lowing:

15 “(ii) Any clinical data and other valid scientific evi-
16 dence, specified in writing by the Secretary to demonstrate
17 reasonable assurance of device effectiveness shall rep-
18 resent a determination by the Secretary that such evidence
19 is the least burdensome information necessary to satisfy
20 a finding of effectiveness for purposes of approving a de-
21 vice under subsection 515(d).”.

22 (b) **INVESTIGATIONAL PLAN AGREEMENT MEET-**
23 **INGS.**—Section 520(g)(7) (21 U.S.C. 360j(g)(7)) is
24 amended—

25 (1) in subparagraph (A)—

1 (A) by striking the first sentence and in-
2 serting the following: “In the case of a person
3 intending to investigate the safety and effective-
4 ness or substantial equivalence of a device, and
5 such investigation includes the undertaking of a
6 clinical trial, the Secretary shall ensure that
7 such person has an opportunity, prior to sub-
8 mitting an application under section 515 or a
9 premarket notification under section 510(k) to
10 the Secretary or an institutional review com-
11 mittee, to submit to the Secretary an investiga-
12 tional plan (including a clinical protocol) for re-
13 view.”; and

14 (B) by striking the last sentence and in-
15 serting the following: “The written request shall
16 include a detailed description of the device, in-
17 cluding the device’s proposed indications or con-
18 ditions of use, and a proposed investigational
19 plan or any part of such plan to which the sub-
20 mitter seeks review and agreement.”; and

21 (2) in subparagraph (B), in the matter pre-
22 ceding clause (i), by inserting after “applicant shall”
23 the following: “reflect the least burdensome informa-
24 tion necessary to support an approval under section

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

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

6 (1) in clause (i), by inserting at the end the fol-
7 lowing: “The term application, as used in this para-
8 graph, shall include any submission made under this
9 section, or regulations implementing this section,
10 which is subject to a 180 day review period.”; and

11 (2) in clause (ii), by inserting at the end the
12 following: “The written identification of deficiencies
13 and the specific information that is required to cor-
14 rect such deficiencies shall be provided to the appli-
15 cant no later than 10 days prior to the meeting.”.

16 **SEC. 9. GUIDANCE.**

17 (a) IN GENERAL.—Section 701(h)(1)(C) (21 U.S.C.
18 371(h)(1)(C)) is amended—

19 (1) by inserting “(i)” after “(C)”; and

20 (2) by adding at the end the following:

21 “(ii)(I) After a request for participation from individ-
22 uals or groups not employed or associated with Federal
23 or State governments to participate in the development of
24 specific guidance or policy documents, the Secretary shall
25 meet with such individuals or groups to obtain input into

1 the guidance development process when such persons or
2 groups have expertise germane to the subject matter of
3 potential guidance or policy documents and, in the opinion
4 of the Secretary, such persons or groups can provide infor-
5 mation that will enhance the Secretary’s public health as-
6 sessment of the impact of a potential guidance or policy
7 document.

8 “(II) Any request under subclause (I) shall identify
9 the expertise, and relevance of such expertise, to the devel-
10 opment of a guidance or policy document, or the informa-
11 tion that would justify a meeting because of the expected
12 benefit to the public health resulting from such informa-
13 tion.

14 “(III) Each meeting with an individual or group
15 under subclause (I) shall be promptly identified through
16 publication of the Secretary’s calendar.”.

17 **SEC. 10. MODULAR REVIEW.**

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

21 “(4)(A) Prior to the submission of an application
22 under this subsection, the Secretary shall accept and re-
23 view portions of such applications that applicants and the
24 Secretary agree are complete and ready for review.

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

7 “(C) Whenever the Secretary determines that a por-
8 tion of a submission under subparagraph (A) is unaccept-
9 able, the Secretary shall specifically identify, in writing,
10 the deficiency of such portion and describe in detail the
11 means by which it may be made acceptable.”.

12 **SEC. 11. REGISTRATION.**

13 (a) IN GENERAL.—Section 510(b) (21 U.S.C.
14 360(b)) is amended to read as follows:

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

22 “(2) Every person who registers under this section
23 shall update such person’s registration information within
24 30 days of any change or event, when information about

1 such change or event is required by regulations promul-
2 gated by the Secretary.

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

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

11 **SEC. 12. ELECTRONIC LABELING.**

12 Section 201(m) (21 U.S.C. 321(m)) is amended by
13 adding at the end the following: “For purposes of pro-
14 viding adequate directions for use, labeling may also in-
15 clude written, printed, or graphic matter which is dis-
16 played by electronic means and is intended as labeling by
17 the person responsible for labeling an article.”.

○