Order Code RL34102

CRS Report for Congress

FDA Legislation in the 110th Congress: A Side-by-Side Comparison of S. 1082 and H.R. 2900

Updated August 6, 2007

Erin D. Williams, Susan Thaul, Sarah A. Lister,
Donna V. Porter, and C. Stephen Redhead
Domestic Social Policy Division

Congressional
Research
Service

Prepared for Members and Committees of Congress

FDA Legislation in the 110th Congress: A Side-by-Side Comparison of S. 1082 and H.R. 2900

Summary

Both the House and the Senate have passed comprehensive legislation to reauthorize existing Food and Drug Administration (FDA) programs and expand the agency's authority to ensure the safety of prescription drugs, medical devices, and biologics. The Senate passed the Food and Drug Administration Revitalization Act (S. 1082) on May 9, 2007. The House passed the Food and Drug Administration Amendments Act of 2007 (H.R. 2900) on July 11, 2007.

At its core, the legislation renews authority for two key user fee programs that are set to expire on October 1, 2007: the Prescription Drug User Fee Act (PDUFA; P.L. 107-188) and the Medical Device User Fee and Modernization Act (MDUFMA; P.L. 107-250). These account for 87% of FDA's user fee revenue and 19% of FDA's total FY2008 program level budget. Without the reauthorizations, and absent a substantial increase in FDA's annual appropriations, the agency would lose a significant source of funding. FDA had warned that a failure to reauthorize the user fee programs before August 1, 2007, would require the agency to issue layoff notices, but the agency has reportedly forestalled that necessity by switching to reserve funds.

In addition to user fee programs, the bills reauthorize two other FDA authorities related to prescription drugs for pediatric populations, which are also set to expire on October 1, 2007: the Best Pharmaceuticals for Children Act (BPCA; P.L. 107-109) and the Pediatric Research Equity Act (PREA; P.L. 108-155). These laws provide marketing exclusivity incentives and requirements for studying pediatric use of on-patent and off-patent drugs. S. 1082 and H.R. 2900 also contain provisions related to drug safety, pediatric medical devices, clinical trial registration, and the creation of a new nonprofit entity to assist FDA with its mission. The bills' overlapping provisions are similar, but not identical.

S. 1082 contains some additional provisions that are not present in H.R. 2900, on the topics of food safety, prescription drug importation, and domestic pet turtle market access. Attempts to expand the legislation to address several other FDA-related issues, for example, follow-on biologics and genetic testing, have thus far been unsuccessful. Differences between the bills may be addressed in conference. This report contains a side-by-side comparison of S. 1082 and H.R. 2900, and includes links to relevant CRS reports. It will be updated as further legislative events warrant.

Contents

List of Tables

FDA Legislation in the 110th Congress: A Side-by-Side Comparison of S. 1082 and H.R. 2900

Introduction

Both chambers of Congress have passed comprehensive legislation to reauthorize expiring programs at the Food and Drug Administration (FDA) and to expand the agency's authority to help ensure the safety of certain medical products. The bills are the Food and Drug Administration Revitalization Act (S. 1082) and the Food and Drug Administration Amendments Act of 2007 (H.R. 2900). S. 1082 and H.R. 2900 represent the most comprehensive FDA legislation since the Food and Drug Administration Modernization Act of 1997 (FDAMA; P.L. 105-115).

The primary driver of the legislation is the renewal of FDA's authority for two key user fee programs set to expire at the end of FY2007: the Prescription Drug User Fee Act (PDUFA; P.L. 107-188) and the Medical Device User Fee and Modernization Act (MDUFMA; P.L. 107-250). FDA had reportedly urged Congress to complete its reauthorization efforts before August 1, 2007 (rather than by the program's termination date of October 1, 2007), because of a requirement that FDA notify employees at least 60 days in advance of layoffs, which would be necessary without PDUFA and MDUFMA funds.[1] The media report that FDA has switched to reserve funds to forestall the issuance of layoff notifications, the effect of which is a hiring freeze at FDA.[2] In addition, the FDA Commissioner has reportedly stressed that the funding uncertainty is harming the morale of employees — 30% of which are at a point where they can retire.

The bills also would reauthorize two other expiring authorities, which are related to pediatric pharmaceuticals: the Best Pharmaceuticals for Children Act (BPCA; P.L. 105-115), reauthorized in P.L. 107- 109, and the Pediatric Research Equity Act (PREA; P.L. 108-155). In addition, the bills address a number of other issues of concern to Congress and the public.

This report presents a side-by-side analysis of S. 1082 and H.R. 2900, highlighting the differences between the bills. It contains individual tables on topics covered by the bills, including prescription drug user fees, medical device user fees, medical device regulation, pediatric exclusivity incentives (BPCA), mandatory

---

[1] Joe Reichard, "FDA Running on Budgetary Fumes, Chief Says" *CQ Healthbeat News*, August 2, 2007, 4:40 p.m..

[2] Anna Edney, "FDA To Avoid Layoff Notices By Dipping Into Reserves," *Congress Daily, Health*, August 2, 2007.

pediatric assessments (PREA), pediatric medical devices, drug safety, antibiotic drugs, clinical trials databases, conflicts of interest, importation of prescription drugs, a new Reagan-Udall Foundation, food safety, domestic pet turtle market access, and other provisions. In general, provisions in the two bills amend FDA's authorities in the Federal Food, Drug and Cosmetic Act (FFDCA) or the Public Health Service Act (PHSA). Unless otherwise noted, mention of "the Secretary" in the following tables refers to the Secretary of Health and Human Services (HHS).

For background information on the impetus for this legislation and for an overview of the two bills, see CRS Report RL34089, *FDA Legislation in the 110th Congress: A Guide to S. 1082 and H.R. 2900*, by Erin D. Williams, Susan Thaul, and Donna V. Porter.

Table 1. Prescription Drug User Fees

Current Law: First enacted in 1992 to provide the FDA with a source of revenue to supplement direct appropriations from Congress, the Prescription Drug User Fee Act and its two reauthorizations have authorized the assessment, collection, and use of application, establishment, and product fees. Authorized uses of the fees have expanded in each reauthorization the activities included in "the review of human drug applications." Initially the funds were for the review of drug approval and biologic licensing applications for marketing. For FY2002 through 2007 (PDUFA III) fees were used for limited postmarket safety activities.

Major Differences Between Bills: The House bill would increase the total user fee revenue allowed by $225 million over FY2008 — FY2012 to be used for drug safety activities; and would decrease that total by the amount of any increased appropriations (excluding fees) for those activities. Note: S. 1082 includes the same revenue total increase as part of its drug safety, rather than its PDUFA, title. The Senate provision, however, does not include the "reverse trigger" (as the House committee members referred to it in discussion) to decrease this additional fee revenue as direct appropriations increase.

CRS Products: CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): Background and Issues for PDUFA IV Reauthorization*, by Susan Thaul.

Topic	S. 1082	H.R. 2900
Location	Title I	
Law amended	FFDCA Sections 735 and 736 (21 U.S.C. 379g and 379h)	
Placement in FFDCA	Places within FFDCA Sec. 735 the requirements that PDUFA I, II, and III incorporated by reference. These are performance goal letters from the Secretary to the congressional committees; and annual fiscal and performance reports.	Continues past practice by including requirements in the bill, with reference to previous authorization bills, but does not amend the FFDCA.
Authorized uses of fees	Adds to the list of postmarket safety activities for which the fees could be used, to include adverse event data collection systems and improved analytical tools, and increased requirements for adverse event reporting, both to the Secretary and to the public.	
		Includes additional items relating to publicly available information, adverse event summary reports, reports to Congress on FDA Office of Surveillance and Epidemiology recommendations, and the development of postmarket safety performance measures.

Topic	S. 1082	H.R. 2900
Annual reports	Requires Secretary to submit an annual performance report and an annual fiscal report to the authorizing congressional committees.	
Publicly available material	Requires that the Secretary make publicly available on the FDA website the annual performance and fiscal reports to congressional committees.	Requires that the Secretary make publicly available on the FDA website the minutes of all negotiations relating to the development of performance goals and plans for meeting the goals between the FDA and the regulated industry and representatives of patient and consumer advocacy groups.
Compounded PET drugs	Creates a reduced annual establishment fee regarding an approved human drug application for a compounded positron emission tomography (PET) drug.	
	Sets fee at one-fifth the annual establishment fee.	Sets fee at one-sixth the annual establishment fee.
Fee revenue amounts	Establishes total prescription drug user fee revenues, for each fiscal year, of $392,783,000, with various adjustments. Amends the adjustment methods for inflation (to include cost of compensation and benefits) and workload (regarding active investigational new drug applications), and adds an adjustment for rent and rent-related costs.	
		Adds to the adjusted fee revenue total, $225 million over FY2008 — FY2012, as specified. If the total FDA appropriation amount (calculated according to specifications and excluding fees) increases, then the allowed fee revenue total would decrease by that amount.
		Exempts from product and facility fees applications for orphan drugs.
User fees for the advisory review of advertisements	Adds a new FFDCA §736A to authorize the assessment and collection of fees relating to advisory review of certain drug advertisements. Manufacturer requests for pre-dissemination review of advertisements would be voluntary, and FDA responses would be advisory. Only manufacturers that request such reviews would be assessed the new fees, which would include an advisory review fee and an operating reserve fee.	
	Section title refers to "prescription drug advertising."	Section title refers to "prescription-drug television advertising."
	Refers to the "initial public dissemination."	Refers to the "initial public broadcast."

Topic	S. 1082	H.R. 2900
	In definition of *direct-to-consumer advertisement*, refers to "to be displayed on any television channel for less than 2 minutes." Elsewhere in bill, the reference to FFDCA 735(3), in this definition, is corrected to FFDCA Section 735(d)(3).	In definition of *direct-to-consumer advertisement*, refers to "to be displayed on any television channel for less than 3 minutes." Does not include a corrected Section number.

Table 2. Medical Device User Fees

Current Law: The Medical Device User Fee and Modernization Act of 2002 amended the FFDCA to establish user fees for premarket reviews of devices. FDA's authority to collect these user fees will expire on October 1, 2007. MDUFMA user fees were attached only to different types of applications to FDA (not to regular annual events, such as registration). MDUFMA also incorporated, by reference, certain performance goals related to the timing of FDA's review of applications, which were established through negotiations between industry and FDA representatives. MDUFMA specifies that FDA may not collect device-related user fees, and is not required to meet associated performance goals, if direct appropriations to FDA for device-related activities fall below a certain threshold.

Major Differences Between Bills: H.R. 2900 excepts Indian tribes from establishment fees. It requires information on postmarket safety in an annual report. S. 1082 requires information on previous cohorts, requires publication of the reports, and writes report requirements into FFDCA. S. 1082 specifies that the Secretary has the sole authority to make user fee refund decisions, and that they are nonreviewable.

CRS Products: CRS Report RL33981, *Medical Device User Fee and Modernization Act (MDUFMA) Reauthorization*, by Erin D. Williams.

Topic	S. 1082	H.R. 2900
Location	Title III, Subtitle A	Title II, Subtitle A
Law Amended	FFDCA Sections 737 (21 U.S.C. 379i) and 738 (21 U.S.C. 379j).	
New Fees	FDA gains the authority to assess three new types of fees: (1) an annual *establishment registration fee* (paid once each year by each manufacturer); (2) an *annual fee* for filing periodic reports (generally applicable to Class III devices — those requiring FDA's highest level of safety controls); and (3) a fee for *30-Day Notices* (submitted for modifications to manufacturing processes or methods, typically only required for Class III devices). Other types of fees required by the FFDCA would remain in place.	
Reduced Fee Amounts	The amounts of individual fees decrease from FY2007 to FY2008. After FY2008, fees will generally increase each year by 8.5%. For the newly created establishment fee, the Secretary could increase the fee amount in FY2010 up to an additional 8.5% over the annual 8.5% increase if fewer than 12,250 establishments paid the fee in FY2009.	
Fee Exceptions	Federal or state governmental entities do not need to pay the new annual establishment registration fees.	
		Governmental fee exception extends to Indian tribes.

Topic	S. 1082	H.R. 2900
Fee Refunds	Secretary may refund portions of fees for modular applications withdrawn before FDA takes its first action, or before other subsequent submissions are made.	
	Secretary has the sole authority to make refund decisions; decisions are not reviewable.	
Fees for Small Businesses	Fee amounts paid by small businesses are further reduced. FDA no longer considers the assets of partners and parent firms when determining whether a company is a small business. Foreign businesses can qualify as small businesses, because FDA may consider evidence of income from sources other than the federal income tax return submitted to the Internal Revenue Service.	
Failure to Pay Fees	The requirement that the Secretary deem incomplete an application from a person with a missing fee, and not accept it until all fees owed by the person are paid, is expanded to encompass the new application fees. Secretary may not deem complete, nor accept, registration information submitted under FFDCA §510 (Registration of Producers of Drugs and Devices) until the registration fee is paid.	
Conditions and Authority	The current restriction that fees may not be assessed and the Secretary is not expected to meet any performance goals if the amount of medical device-related direct appropriations falls below a specified threshold ($205,720,000 multiplied by an annual adjustment factor), is extended through FY2012. Also extended through FY2012, a provision allowing that if the Secretary is prevented from collecting fees during any portion of a fiscal year because of insufficient direct appropriations but may collect them later during that fiscal year, the Secretary may then begin collecting fees without any modification in the rate.	
	Statutory language specifying the calculation for previous years is struck.	
Crediting and Availability of Fees	The following amounts of user fees are authorized to be collected: $48,431,000 for FY2008; $52,547,000 for FY2009; $57,014,000 for FY2010; $61,860,000 for FY2011; and $67,118,000 for FY2012. FDA is allowed to aggregate all fees collected between FY2008 and FY2011 and compare that amount to the aggregate amount authorized for the same period. A reduction will be made in fees in the final year only if the amount collected in the four-year period exceeds the amount authorized for the same period, rather than a reduction being made any year that fees collected exceed the authorized appropriation.	

Topic	S. 1082	HR. 2900
Annual Report	A requirement is continued through FY2013 that the Secretary submit annual progress reports to relevant congressional committees regarding the progress of FDA in achieving fee-related performance goals specified in a letter from the Secretary, and regarding the implementation of the authority to collect such fees.	
	The report includes information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications, supplements, and premarket notifications in the cohort. Performance goal and implementation reports are made available to the public. Report requirements are written into the FFDCA.	The report includes a description of the use of such fees for postmarket safety activities
	In FDA's development of its recommendations to the Congress for FDA performance goals and plans for meeting those goals, FDA must again consult with an array of governmental, professional and consumer groups, publish its recommendations in the Federal Register, provide a public comment period, and hold a public meeting.	
	Recommendations shall be revised upon consideration of public comments. Recommendations must be transmitted to Congress. Consultation requirements written into the FFDCA.	
Postmarket Safety Information Authorization		Additional appropriations authorized for FY2008 — FY2012 of such sums as may be necessary for collecting, developing, reviewing, and evaluating postmarket safety information on medical devices.
Effective Date	October 1, 2007; however, fees will be assessed at the MDUFMA 2002 rate for all premarket applications, premarket reports, supplements, and premarket notification submissions received on or after October 1, 2002 but on or before October 1, 2007, and accepted by FDA for filing prior to the beginning of FY2008.	Effective date is date of enactment; however, fees are assessed for all premarket applications, premarket reports, supplements, and premarket notification submissions received on or after October 1, 2007.
Sunset Clause	Authorization to collect user fees expires on October 1, 2012. Annual report requirements would cease to be effective on January 31, 2013.	
	Expiration dates are written into the FFDCA.	

Table 3. Medical Device Regulation

Current Law: In addition to authorizing the collection of user fees, the Medical Device User Fee and Modernization Act of 2002 amended the FFDCA to allow establishment inspections to be conducted by accredited persons (third parties), and to institute new regulatory requirements for reprocessed single-use devices.

Major Differences Between Bills: S. 1082 would require electronic registration of medical devices only upon a finding by the Secretary that the electronic receipt of such registrations is feasible, whereas H.R. 2900 would require electronic registration as a default, unless the Secretary determined that it was not feasible. H.R. 2900 would require two reports by the Comptroller General: (1) on the use of the 510(k) process to determine whether a new device is safe and effective, and (2) on device-caused nosocomial (i.e., hospital-acquired) infections. H.R. 2900 would require the Secretary to promulgate regulations requiring the labeling of devices to bear a unique identifier. H.R. 2900 would require certain device manufacturers and importers to submit device malfunction reports pursuant to the *medical device reporting* requirements (21 C.F.R. 803) or other criteria established by the Secretary.

CRS Products: CRS Report RL33981, *Medical Device User Fee and Modernization Act (MDUFMA) Reauthorization*, and CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, both by Erin D. Williams.

Topic	S. 1082	H.R. 2900
Location	Title III, Subtitle B	Title II, Subtitle B
Law Amended	FFDCA Sections 704(g) (21 U.S.C. 374(g)); 523(c) (21 U.S.C. 360m(c)); FFDCA Sections 510 (21 U.S.C. 360).	FFDCA Sections 704(g) (21 U.S.C. 374(g)); 523(c) (21 U.S.C. 360m(c)); FFDCA Sections 510 (21 U.S.C. 360); FFDCA Section 519 (21 U.S.C. 360i).
Third Party Premarket Notification Review	The authority for accredited third parties to review premarket notification is extended through FY2012.	
Registration	Foreign and domestic producers of devices are required to register with the Secretary between October 1 and December 31 of each year instead of by December 31 of each year.	
Lists of Devices	Those who register with the Secretary must provide a list of drugs and devices on which they perform specific functions, such as manufacturing and compounding, once per year between October 1 and December 31, instead of once during the month of June and once during the month of December.	

Topic	S. 1082	H.R. 2900
Drug Electronic Registration and Listing	With regard to any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug, registrations under subsections (b), (c), (d), and (i) of this section (including the submission of updated information) shall be submitted to the Secretary by electronic means, *upon a finding by the Secretary that the electronic receipt of such registrations is feasible*, unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.	Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.
Device Electronic Registration and Listing	With regard to any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, the registration and listing information required by this section shall be submitted to the Secretary by electronic means, unless the Secretary grants a waiver because electronic registration and listing is not reasonable for the person requesting such waiver.	
GAO Report		The Comptroller General conducts and submits to Congress a study on the appropriate use of the premarket notification [510(k)] process as part of the device classification process to determine whether a new device is as safe and effective as a classified device.
Unique Identification System		The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the labeling of devices to bear a unique identifier.
Frequency of Reporting for Certain Devices		Certain device manufacturers and importers must submit to the Secretary device malfunction reports pursuant to the *medical device reporting* requirements (21 C.F.R. 803) or other criteria established by the Secretary.

Topic	S. 1082	H.R. 2900
Inspections by Accredited Third Persons	Requirements for inspections by accredited third parties are revised in three ways: (1) by reducing administrative requirements associated with qualifying for the program; (2) by expanding participation in the program; (3) by permitting device companies to voluntarily submit to FDA reports by third parties assessing conformance with an appropriate international quality systems standard. such as those set by the International Standards Organization. FDA would consider the information in these reports in setting its inspection priorities.	
Study of Nosocomial Infections Relating to Medical Devices		The Comptroller General will conduct and submit to Congress a study on infections acquired while individuals are patients at a hospital and were neither present nor incubating in the patient prior to receiving medical treatment.

Table 4. Pediatric Research Incentives (BPCA)

Current Law: Section 505A, added to the FFDCA in 1997, authorizes FDA to give an additional six-month period of marketing exclusivity to a manufacturer in return for FDA-requested pediatric use studies and reports. Amended in 2002, Section 505A also provides mechanisms (though, not necessarily resources) to fund studies of off-patent drugs or drugs whose sponsors have declined FDA's request.

Major Differences Between Bills: The Senate bill would limit the period of exclusivity for a drug to three months if its manufacturer/sponsor had more than $1 billion in annual gross U.S. sales for all its products with the same active ingredient. The House bill would continue the six-month period of exclusivity that is in current law.

CRS Products: CRS Report RL33986, *FDA's Authority to Ensure That Drugs Prescribed to Children Are Safe and Effective*, by Susan Thaul.

Topic	S. 1082	H.R. 2900
Location	Title IV, Subtitle A — Best Pharmaceuticals for Children	Title V — Best Pharmaceuticals for Children Act of 2007
Laws amended	FFDCA Section 505A (21 U.S.C. 355a) and Section 735(6) (21 U.S.C. 379g). PHSA Section 409I (42 U.S.C. 284m) and Section 499(c)(1)(C) (42 U.S.C. 290b(c)(1)(C)).	
Preclinical studies	Refines the study scope to allow the Secretary to include preclinical studies.	
Age groups of interest; labeling changes	Authorizes the Secretary to grant additional marketing exclusivity, for both new drugs and drugs already on the market, only after a sponsor completes and reports on the studies that the Secretary has requested in writing (including appropriate formulations of the drug for each age group of interest), and after any appropriate labeling changes are approved, all within the agreed upon time frames.	
Existing exclusivities	Excepts from exclusivity any drug with another exclusivity that is to expire in less than a specified amount of time.	
	Sets cut-off at less than nine months.	Sets cut-off at less than one year.
Ethnic and racial minorities	Requires that the Secretary, in making study requests, consider the adequate representation of children of ethnic and racial minorities.	
Reasons for not completing studies	Requires supporting evidence if an applicant turns down a request on the grounds that developing appropriate pediatric formulations of the drug is not possible.	

Topic	S. 1082	H.R. 2900
Adverse event reports	Requires applicants to submit, along with the report of requested studies, all postmarket adverse event reports regarding that drug.	
	Requires the Director of Pediatric Therapeutics to provide adverse event reports to the Pediatric Advisory Committee for review and recommendations to the Secretary for action.	
Toll-free number for consumer reports of adverse events	Requires that the rule proposed by the FDA Commissioner on April 22, 2004, take effect on January 1, 2008, unless the Commissioner issues the final rule before that date. Excluded from the rule's application are a drug approved under FFDCA Section 505, a nonprescription drug, and a drug whose packaging includes a toll-free number with which to report adverse events to the manufacturer or distributor.	
Public notice	Expands the public notice requirement beyond the current notice of an exclusivity decision to include copies of the written request.	
	Requires the Secretary to publicly identify any drug with a developed pediatric formulation that studies have demonstrated to be safe and effective for children if its sponsor has not introduced the pediatric formulation onto the market within one year.	
Internal committee	Requires that the Secretary establish an internal review committee, composed of FDA employees with specified expertise.	
	Refers to "pediatric ethics" as a possible expertise to include.	Requires an expert in pediatric ethics.
	Requires that the internal committee review all written requests.	
	Requires that the internal committee also: (1) review all studies and reports submitted pursuant to this provision; and (2) make recommendations to the Secretary on whether to accept or reject the studies.	
Tracking of studies and labeling changes	Requires the tracking of pediatric studies and labeling changes according to specified questions.	
	Requires that the internal committee perform this task.	Assigns that responsibility to the Secretary.
	In addition to information on what was done, would require information concerning when the Secretary did not follow the internal committee's recommendations.	
Exclusivity adjustment	Limits the period of exclusivity for a drug to three months if its sponsor has more than $1 billion in annual gross U.S. sales for all its products with the same active ingredient.	Continues the six-month exclusivity that is in current law.

Topic	S. 1082	H.R. 2900
Dispute resolution	Establishes a dispute resolution process to include referral to the Pediatric Advisory Committee.	
Labeling	Requires that, for a product studied under this section, the labeling include study results (if they do or do not indicate safety and effectiveness, or if they are inconclusive) and the Secretary's determination.	
	Requires dissemination of labeling change information to health-care providers.	
When studies not completed	When studies of a drug with a current patent are not done, requires the Secretary to determine whether to require an assessment under FFDCA Section 505B; otherwise, requires the Secretary, if funds are available from the Foundation for the NIH, to refer the study to the Foundation.	When studies of a drug with a current patent are not done, requires the Secretary to determine whether to require an assessment under FFDCA Section 505B.
	If the drug has no patent in effect, requires the Secretary to refer the drug for inclusion on the list established under PHSA § 409I.	If a drug has no patent in effect, requires the Secretary, if prescription drug user fee funds are available, to award a grant to conduct the study; otherwise, to refer the drug for inclusion on the list established under PHSA § 409I;.
Public notice	Requires the Secretary to report (1) decisions not to issue a written request, and (2) referrals to NIH under PHSA Section 409I.	
		Requires that the notice include the drug's name, manufacturer, and the indications to be studied.
Reports	Requires a study and report from the Institute of Medicine (IOM).	
		Directs that the IOM report include recommendations for incentives for encouraging pediatric studies of biologics.
	Requires a report from the Government Accountability Office.	
Approved drugs for which pediatric studies are needed	Regarding the requirement that the Secretary, through the NIH Director and in consultation with the FDA Commissioner, list approved drugs for which pediatric studies are needed to assess safety and effectiveness. The bills would change the specifications from an annual list of approved drugs to a list, revised every three years, of priority study needs in pediatric therapeutics, including drugs or indications. They would direct the Secretary to fund studies on those issues.	

Topic	S. 1082	H.R. 2900
Authorization for Appropriations	For activities pursuant to PHSA Section 409I, authorizes $200 million for FY2008 and such sums as may be necessary for the subsequent four fiscal years.	
User fees		Authorizes the use of prescription drug user fee revenue for contracted pediatric studies not conducted by a drug's sponsor.
Training	Adds pediatric pharmacological research to the areas covered by the Pediatric Research Loan Repayment Program (PHSA Section 452G(2)).	No provision.

Table 5. Mandatory Pediatric Assessments (PREA)

Current Law: Requires a manufacturer, when submitting an application to market a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, to submit a pediatric assessment. The submission must be adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations; and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. There are specified situations in which the Secretary may waive or defer the requirement. If the disease course and drug effects are sufficiently similar for adults and children, the HHS Secretary may allow extrapolation from adult study data as evidence of pediatric effectiveness, usually supplemented with other data from children, such as pharmacokinetic studies.

For products on the market, the Secretary may require the manufacturer to submit a pediatric assessment in situations in which not having pediatric use information on the label could pose significant risks. Before requiring an assessment, the Secretary must have issued a written request under FFDCA Section 505A or PHSA Section 409I, and the manufacturer must not have agreed to conduct the assessment. If a manufacturer does not comply with the Secretary's notice of a required study, the Secretary may consider the product misbranded.

Major Differences Between Bills: Current law links the program's authorization to the five-year authority it provides to the pediatric exclusivity program. The House bill would eliminate that connection; the Senate bill would continue it.

CRS Products: CRS Report RL33986, *FDA's Authority to Ensure That Drugs Prescribed to Children Are Safe and Effective*, by Susan Thaul.

Topic	S. 1082	H.R. 2900
Location	Title IV, Subtitle B Pediatric Research Improvement	Title IV Pediatric Research Equity Act of 2007
Law amended	FFDCA Section 505B (21 U.S.C. 355c)	

Internal committee	Requires the Secretary to establish an internal committee, composed of FDA employees with specified expertise, to participate in the review of pediatric plans and assessments, deferrals, and waivers.	
	Requires documentation of the internal committee's activity, tracking of pending assessments, and the placement of the information on the FDA website for easy public access.	
	Requires that the internal committee perform these tasks.	Assigns that responsibility to the Secretary.
		Requires that the internal committee conduct a retrospective review and analysis of assessments, deferrals, and waivers to the Secretary, who would be required to issue recommendations for improvements.
Priority applications	For assessments that result in labeling changes, requires FDA to consider as priority applications the manufacturers' supplemental applications to make those changes.	
Dispute resolution	Establishes a dispute resolution procedure for when a sponsor does not agree with the FDA Commissioner's request for a label change; in those cases, requires the Commissioner to refer the dispute to the Pediatric Advisory Committee for review and recommendation. If the sponsor continues to disagree with a requested labeling change, the Commissioner may deem the drug to be misbranded.	
		Requires that the Commissioner refer the dispute to the Pediatric Advisory Committee within 30 days of a sponsor's disagreeing to change the label.
Dissemination	Includes various provisions involving dissemination of assessment findings to the public and health-care providers.	
Adverse events	Includes reporting requirements for adverse events, and their review by the Office of Pediatric Therapeutics and, if requested, the Pediatric Advisory Committee.	

Reports	Requires a study and report from the Institute of Medicine.	
	Requires a report from the Government Accountability Office (GAO).	
	GAO report due by Sept. 1, 2010.	GAO report due by Sept. 1, 2011.
		Include whether the number of FDA's written requests that sponsors decline increased or decreased under these amendments.
		Include a description of the Secretary's actions, recommendations, and efforts to increase neonatal studies.
Authorization	As in current law, links the authority to carry out the above provisions to the five-year authority provided to the pediatric exclusivity program.	Eliminates the provision linking the authority to carry out the above provisions to authorization of the pediatric exclusivity program.

Table 6. Pediatric Medical Devices

Current Law: The process of approving new medical devices for marketing in the United States is generally governed by the FFDCA, Chapter V. Medical devices may be tested in clinical trials demonstrating their *safety and effectiveness*, leading to FDA *approval* for marketing, or demonstrated to be *substantially equivalent* to a device already on the market, leading to FDA *clearance* for marketing. Applications related to devices intended to treat pediatric populations are currently exempted from user fees according to FFDCA § 738(a)(2)(B)(v) — pediatric conditions of use. Devices designed for small patient populations may qualify for the *Humanitarian Device Exemption (HDE)*, that waives the effectiveness requirement and user fees (21 U.S.C. 360j(m)). HDE manufacturers are prohibited from selling their devices for an amount that exceeds the costs of research and development, fabrication, and distribution of the device. The price is dependent on the estimated number of devices to be sold. The Secretary sets this number for each device, and it may not exceed 4,000. Device applications related solely to *pediatric conditions of use* are exempt from fees (FFDCA 738 (a)(2)(B)(v)).

Major Differences Between Bills: S. 1082's modification to the HDE expires in 2012; H.R. 2900's expires in 2013. H.R. 2900 requires an annual review of pediatric HDEs to ensure that they remain appropriate. H.R. 2900 requires the FDA Commissioner to create a plan for expanding pediatric medical device research and development. H.R. 2900 enables a manufacturer to request dispute resolution of certain orders or conditions requiring postmarket surveillance, during which time the device shall not be deemed misbranded unless necessary to protect the public health. S. 1082 requires demonstration grant recipients to report annually to the Secretary on the effectiveness of their activities. S. 1082 requires Office of Pediatric Therapeutics to submit a plan for expanding pediatric medical device research and development. The bills contain different conditions for when the Secretary may require a postmarket study as a condition of pediatric device approval.

CRS Products: CRS Report RL32826, *The Medical Device Approval Process and Related Legislative Issues*, by Erin D. Williams.

Topic	S. 1082	H.R. 2900
Location	Title IV, Subtitle C	Title III
Law Amended	FFDCA chapter V (21 U.S.C. 351 et seq.): Sections 520(m) (21 U.S.C. 369j(m)) and 522 (21 U.S.C. 360l). BPCA Sections 6(b) (21 U.S.C. 393a(b)) and 14 (42 U.S.C. 284m note).	
		PHSA Section 402(b) (42 U.S.C. 282 (b))

Topic	S. 1082	H.R. 2900
New Devices	Certain applicants are required to include, if readily available, a description of any *pediatric subpopulations* (neonates, infants, children or adolescents — defined in amended §520(m)(6)(E)(ii)) that suffer from the condition the device is intended to treat, and the number of affected pediatric patients. Requirements apply to persons submitting an application to FDA under one of two FFDCA sections: (1) § 515 — a premarket application (PMA) to market a class III device (class III devices are those that require FDA's highest level of safety controls); (2) § 520(m) — an HDE application.	
Annual Report	The Secretary submits an annual report to the Senate Health, Education, Labor, and Pensions (HELP) and House Energy and Commerce Committees that includes, for the preceding year: (1) the number of devices approved for which a pediatric subpopulation suffers from the disease or condition the device is intended to treat; (2) the number of devices labeled for pediatric use; (3) the number of approved pediatric devices exempted from a fee pursuant to *pediatric conditions of use*; and (4) the review times for applications described above.	
Determination of Pediatric Effectiveness	The Secretary may conclude that adult data can be used to support a reasonable assurance of effectiveness in pediatric subpopulations, as appropriate.	
Subpopulation Extrapolation	A study for each pediatric subpopulation may not be necessary if data from one could be extrapolated to another.	
Modification to Humanitarian Device Exemption	A person granted an HDE is permitted to sell his device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device if the following criteria were met: (1) the device is intended to treat and is labeled for use in a pediatric subpopulation; (2) the device was not approved for pediatric use prior to the act's date of enactment; (3) the number of devices distributed does not exceed a distribution number specified by the Secretary that may not exceed the number specified by the Secretary for the HDE; (4) the applicant immediately notifies the Secretary if the number of devices distributed exceeds the allowable annual distribution number; and	
	(5) the request is submitted on or before October 1, 2012.	(5) the request is submitted on or before October 1, 2013.
Pediatric HDE Compliance, Inspection	If a person fails to demonstrate continued compliance with pediatric HDE requirements, the Secretary must provide notice and an opportunity for a hearing before suspending or withdrawing exemption from effectiveness requirements. The Secretary may inspect the records relating to the number of devices distributed during any calendar year for any person granted an HDE exemption from effectiveness requirements under the new pediatric rule. A person may petition the Secretary to change, and the Secretary may modify up to 4,000, the number of devices sold under the new pediatric HDE. If the Secretary discovers through notification or inspection that the number of devices marketed exceeded the projected annual distribution number, the sale price restriction will apply from that point forward.	

Topic	S. 1082	H.R. 2900
Pediatric HDE and the Office of Pediatric Therapeutics	Requires the Secretary to report adverse events regarding devices granted a pediatric HDE to the Office of Pediatric Therapeutics (OPT). OPT Director provides a periodic review of the reports by the Pediatric Advisory Committee, obtains the Committee's recommendations, and reports back to the Secretary.	
		OPT provides for an annual review by the Committee of all devices granted the pediatric HDE to ensure that the exemption remains appropriate.
Comptroller General Report	By January 1, 2012, the Comptroller General submits a report to the Senate HELP and House Energy and Commerce Committees on the impact of the new pediatric HDE, including, among other elements:	
	An evaluation of demonstration grants for improving pediatric device availability (required by the bill) *that have been or are being studied in children, and that have been submitted to the FDA for approval, clearance, or review under an HDE (FFDCA Section 520(m), as modified by this Act) and any regulatory actions taken.*	An evaluation of the demonstration grants for improving pediatric device availability (required by the bill).
Guidance	Within 180 days of enactment, requires the FDA Commissioner to issue guidance for institutional review committees on how to evaluate requests for approval for devices for which an HDE has been granted.	
Point of Contact for Available Funding	*NIH Director's duties are modified in PHSA*, requiring the Director to designate a point of contact or office to help innovators and physicians *identify some sources of funding available* for pediatric medical device development (42 U.S.C. 282(b)).	NIH Director shall designate a point of contact or office *at the NIH* to help innovators and physicians *access funding* for pediatric medical device development.
Plan for Pediatric Medical Device Research		Requires the FDA Commissioner, in collaboration with various agency heads, to submit to the Senate HELP and House Energy and Commerce Committees a plan for expanding pediatric medical device research and development. (Contents specified in bill).

Topic	S. 1082	H.R. 2900
Demonstration Grants	Within 90 days of enactment, requires the Secretary to issue a *request for proposals* (RFP) for one or more grants or contracts to nonprofit consortia for demonstration projects to promote pediatric device development. Secretary determines application content and submission time and manner. Within 180 days of RFP, requires the Secretary to make a determination on the grants or contracts.	
	A nonprofit consortium that receives a grant or contract under this section shall *facilitate the development, production, and distribution of devices by* — (list of requirements parallel to H.R. 2900 except): *(5) providing assistance and advice as needed on business development, personnel training, prototype development, postmakret needs, and other activities consistent with the purposes of this section.*	A nonprofit consortium that receives a grant or contract under this section shall — (list of requirements parallel to S. 1082 except): *(5) assess business feasibility and provide business advice;* *(6) provide assistance with prototype development; and* *(7) provide assistance with postmarket needs, including training, logistics and reporting*
Coordination of Demonstration Grants	Requires that grantees coordinate with the NIH point of contact for available funding (created by the act), and provide NIH with identified pediatric device needs the consortium lacks the capacity to address, or in which the consortium has been unable to stimulate manufacturer interest. Grantees coordinate with the FDA Commissioner to facilitate the application for approval of devices labeled for pediatric use.	
	Requires that grantees report annually to the Secretary on the effectiveness of their activities, their impact on pediatric device development, and the status of pediatric device development facilitated by the consortium.	
Demonstration Grant Authorization	Authorizes the appropriation of $6,000,000 for each of FY2008 through FY2012 to carry out the pediatric medical device demonstration grant activities called for in the act.	
Office of Pediatric Therapeutics	The duties of FDA's OPT are expanded to include increasing pediatric access to medical devices.	
	Requires OPT, in collaboration with the directors of other specified agencies, to submit to the Senate HELP and House Energy and Commerce Committees a plan for expanding pediatric medical device research and development, including the current status of, gaps in, and a plan for improving pediatric medical device development, product approval or clearance, and evaluation of safety and effectiveness.	
Pediatric Advisory Committee	Expands the Secretary's authority to convene and consult an advisory committee on pediatric therapeutics specifically to include the topic of increasing access to pediatric medical devices.	

Topic	S. 1082	HR. 2900
Postmarket Surveillance	The *surveillance approval* paragraph of the medical device *postmarket surveillance* section of the FFDCA (522; 21 U.S.C. 360l) is amended to allow for the Secretary to require, as a condition of approval, postmarket studies of longer than 36 months for devices that are expected to have a significant use in pediatric populations, if the extended time is necessary to assess the safety of the device. The *in general* paragraph, which gives the Secretary authority to order postmarket studies, is amended to include pediatric medical devices as follows:	
	1) IN GENERAL- (A) CONDUCT- The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that is a class II or class III device — (i) the failure of which would be reasonably likely to have serious adverse health consequences; (ii) that is expected to have significant use in pediatric populations; or (iii) that is intended to be — (I) implanted in the human body for more than 1 year; or (II) a life-sustaining or life-supporting device used outside a device user facility. (B) CONDITION- The Secretary may order a postmarket surveillance under subparagraph (A) as a condition to approval or clearance of a device described in subparagraph (A)(ii). `(2) RULE OF CONSTRUCTION- The provisions of paragraph (1) shall have no effect on authorities otherwise provided under the Act or regulations issued under this Act.'	(a) IN GENERAL. — The Secretary may by order or as a condition to approval of an application (or a supplement to an application) or a product development protocol under Section 515 or as a condition to clearance of a premarket notification under Section 510(k), for a pediatric population or pediatric subpopulation, require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences, or that is indicated for pediatric populations or subpopulations or is expected to have significant use in pediatric populations, or which is intended to be — (1) implanted in the human body for more than one year, or (2) a life-sustaining or life-supporting device used outside a device user facility.
Dispute Resolution		Permits a manufacturer to request a review under FFDCA Section 562 (dispute resolution) of any order or condition requiring postmarket surveillance under this section, during which time the device shall not be deemed misbranded under Section 502(t) or otherwise in violation of such order or condition or a related requirement of this act unless necessary to protect the public health.

Table 7. Drug Safety

Current Law: Since 1938, the Federal Food, Drug, and Cosmetic Act (FFDCA) has required that drugs be safe and, since 1962, that they be effective (which is relevant to safety for drugs that have adverse as well as beneficial effects). The FFDCA gives FDA the authority to regulate drugs (and biologics licensed under the Public Health Service Act), including clinical testing, marketing approval and postmarketing safety and effectiveness monitoring. Current law allows FDA to require a postmarket study as a condition of its initial approval of a marketing application, but does not authorize FDA to add such requirements after approval. Current law does not provide for civil penalties, authorizing only the revocation of approval or licensing (or the threat of revocation) to compel manufacturers to change labeling or advertising. FDA does not have the authority to require manufacturers to submit advertising material for review or approval before dissemination.

Major Differences Between Bills: The bills differ mostly in their details rather than in their basic approach. They vary in their authorization of civil penalties and funding. A few provisions appear in only one or the other bill.

CRS Products: CRS Report RL32797, *Drug Safety and Effectiveness: Issues and Action Options After FDA Approval*, by Susan Thaul.

Topic	S. 1082	H.R. 2900
Location	Title II — Drug Safety. Subtitle A — Risk Evaluation and Mitigation Strategies (REMS)	Title IX — Risk Evaluation and Mitigation Strategies (REMS)
Laws amended	Amends FFDCA Sections 303 (21 U.S.C. 333), 502 (21 U.S.C. 352), 505 (21 U.S.C. 355), 735 (21 U.S.C. 379g), and 736 (21 U.S.C. 379h). Adds FFDCA Sections 506D and 566. Amends PHSA Section 351 (42 U.S.C. 262).	Amends FFDCA Sections 301 (21 U.S.C. 331), 303 (21 U.S.C. 333), 502 (21 U.S.C. 352), and 505 (21 U.S.C. 355). Adds FFDCA Sections 503B, 505-1, and 511. Amends PHSA Section 351 (42 U.S.C. 262).

Topic	S. 1082	H.R. 2900
Postmarket studies and clinical trials	Authorizes the Secretary to require postapproval studies or clinical trials.	
	Included as a potential REMS element.	Is not included within the REMS provisions.
	Requires that the Secretary, to require a postapproval study or clinical trial, make the determination that other reports or surveillance would be inadequate to assess a signal of serious risk or to identify unexpected serious risks.	Requires that the Secretary, to require a postapproval study or clinical trial to assess a known serious risk or signals of serious risk, or to identify a serious risk, make the determination on the basis of scientific information.
		Authorizes the Secretary to require a postapproval study or clinical trial after learning of new safety information to include timetables and periodic reports. Requires a sponsor that fails to comply with such requirements to demonstrate good cause.
	Requires that any trial required under this section be included in the clinical trial registry data bank.	
Labeling changes	Authorizes the Secretary, upon learning of new relevant safety information, to require that the sponsor submit a supplement for a labeling change; creates procedures, including time limits, for notification, review, dispute resolution, and violation.	
	Included as a new FFDCA Section 506D.	Amends FFDCA Section 505.

Topic	S. 1082	H.R. 3580
Risk evaluation and mitigation strategies (REMS)	Authorizes the Secretary to require that the sponsor of a drug or biologic application or supplement to an application submit a proposed REMS. Authorizes the Secretary to require a REMS, with fewer elements, for a product under an abbreviated new drug application.	
		Prohibits the sale of a new drug or biologic if it is not in compliance with an approved REMS or if the sponsor fails to conduct a postmarket study that is required following approval under subpart H of 21 U.S.C. 314.
		Requires a sponsor to submit a statement along with an application about whether it believes a REMS should be required.
	Requires a sponsor to submit a REMS if the Secretary (acting through the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug) determines that, based on a signal of a serious risk with the drug, it is necessary to assess such signal or mitigate such serious risk.	Pre-approval: If the Secretary determines such a strategy is necessary to ensure that the benefits of the drug involved outweigh the risks of the drug. Postapproval: If the Secretary becomes aware of new safety information and determines a REMS necessary. The Secretary's authority also extends to an application for a new indication for use and an abbreviated new drug application.
		Regarding noncompliance with a REMS requirement that had been added after a product's approval, after notice and opportunity for a hearing, requires the Secretary to publish in the *Federal Register* a statement of noncooperation.
	Requires a sponsor to submit a REMS if the Secretary determines from data or information in an application that the following are necessary: postapproval studies or clinical trials, information to patients or clinicians, pre-review of advertisements, disclosures in advertisements, or ensuring access.	

Topic	S. 1082	H.R. 2900
REMS core elements	Requires assessments of an approved REMS.	
	No less frequently than 18 months and 3 years after a drug is initially approved; and, subsequently, at a frequency (including none) as the Secretary determines.	No less frequently than once annually for the first 3 years after the REMS is approved; in the seventh year; and, subsequently, at a frequency (including none) as the Secretary determines.
	Product labeling.	
REMS optional elements	*Information to patients*, to include Medication Guide and patient package insert.	
	Communication plan to health care providers, such as letters, information about REMS, and explanations of safety protocols.	
	Restrictions on distribution or use; along with a system to monitor implementation, the Secretary's evaluation of the elements to assure safe use, waiver for use of certain medical countermeasures in the time a declared public health emergency, and minimizing burdens on patient access to a drug and on the health care delivery system.	
	Allows expanded access for an off-label use for a serious or life-threatening disease or condition. Allows safe access to drugs with known serious risks that would otherwise be unavailable.	
		Includes a few provisions regarding how any restrictions on the distribution of an approved drug relate to generic drug applications; for example, prohibits a sponsor from using a restriction on distribution to block or delay approval of a generic drug application.
	Postapproval studies or clinical trials	[Included in separate, non-REMS, section.]
	Preview of advertisements	[Included in separate, non-REMS, section.]

Topic	S. 1082	H.R. 2900
REMS assessments	Permits a sponsor to submit a voluntary assessment of an approved REMS at any time.	
	Requires assessments at prearranged times; and when the Secretary determines that new information indicates an existing element should be modified or included.	
	Requires that the Secretary's determination be based on new safety information.	Requires that the Secretary's determination be based on new safety or effectiveness information.
	Requires an assessment of how well the elements to assure safe use are meeting the goal of increasing safe access to drugs with known serious risks and whether the goal or such elements should be modified; and an assessment of the status of required postapproval studies and clinical trials.	
REMS modifications	Allows modifications to include the assessment timetable; or the addition, modification, or removal of a restriction on distribution or use.	
	Allows other modifications: a labeling change; the addition or modification of a postapproval study or clinical trial requirement; or the addition, modification, or removal of an element on advertising, or an element to assure safe use.	
		Does not require a REMS assessment for a labeling change for which a supplemental application is not required, or for which distribution of the drug may commence upon the receipt by the Secretary of a supplemental application for the change.

Topic	S. 1082	H.R. 2900
REMS review	Amends the FFDCA (S. 1082 places it as a new paragraph 505(o); H.R. 2900 creates a new Section 505-1) to require that the Secretary promptly review each proposed REMS and each assessment of an approved REMS. Specifies the procedures, including timeframes, for that review. These include dispute resolution, including review by a Drug Safety Oversight Board (made up of federal government scientists and health care practitioners), use of advisory committees, and administrative appeals; addressing drug class effects; and coordinating assessment timetables with efforts of other countries.	
	Requires that a dispute resolution occurring before an initial approval follow procedures set forth in the letters described in FFDCA Section 735(a).	
		Authorizes the Secretary to require a sponsor, as part of a REMS review, to submit information regarding its *marketing plan and practices for the drug*, so as to allow the Secretary to determine whether any of the proposed or ongoing marketing activities undermine any of the requirements of the REMS. Does not authorize the Secretary to make or direct any change in the marketing plan or practices involved.
REMS noncompliance	S. 1082 Section 202 — for FFDCA Section 505(o)(9): For an applicant that knowingly fails to comply with a requirement of an approved REMS, creates a *civil monetary penalty* of $250,000 for the first 30-day period that the applicant is in noncompliance, with such amount doubling each 30-day period thereafter that the requirement is not complied with, not to exceed $2 million.	No civil monetary provision within the REMS sections (i.e., FFDCA 505(o), 505(p), or 505-1).
Advertisements: Prereview	Authorizes the Secretary to require a prereview (at least 45 days before dissemination) of advertisements to ensure the inclusion of a true statement of information in brief summary relating to a serious risk listed in the labeling of a drug, or relating to a protocol to ensure the safe use described in the labeling of the drug.	
	A potential element of a REMS.	New FFDCA Section 503B.
	Refers to "advertisements."	Refers to "television advertisement."
		Does not authorize the Secretary to make or direct changes in any material submitted pursuant to this section.
		Requires the Secretary to take into consideration the impact of the advertised drug on elderly populations, children, and racially and ethnically diverse communities.

Topic	S. 1082	H.R. 2900
Advertisements: Required disclosures	Authorizes the Secretary to *require inclusion of a disclosure* in an advertisement if the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a *serious risk* listed in the labeling of the drug involved.	
	Includes authority to require a disclosure concerning a *protocol to ensure safe use* as described in the drug's labeling.	
	Authorizes the Secretary to require the advertisement to include a specific disclosure of the *approval date* if the Secretary determines that the advertisement would otherwise be false or misleading.	
	Does not specify a time limit for the approval date disclosure.	Specifies that the approval date disclosure may not to exceed 2 years from the date of the drug's approval.
	If the Secretary requires a specific disclosure as part of a REMS, the Secretary must: (1) consider identifying and assessing all serious risks of using the drug to be a priority safety question under the surveillance and assessment section of FFDCA; (2) not less frequently than every 3 months, evaluate surveillance reports to determine whether serious risks that might occur among patients expected to be treated with the drug have been adequately identified and assessed; (3) remove the disclosure requirement if risks have been adequately identified and assessed; and (4) consider whether the disclosure should be required.	
	S. 1082 Sec. 519(b); H.R. 2900 Sec. 901(b). Amends FFDCA Sec. 502(n), for a television or radio direct-to-consumer (DTC) advertisement of a prescription drug that states the name of the drug and its conditions of use, to require that the major statement relating to side effects and contraindications be presented in a *clear and conspicuous manner*.	
	Inserts "(neutral)" between "clear and conspicuous" and "manner." (See previous row.)	
Advertisements: Toll-free number		Amends FFDCA Section 502(n) to require that any DTC advertisement include the following statement: "You are encouraged to report adverse effects of prescription drug medication to the FDA. Log onto [http://www.fda.gov/medwatch] or call 1-800-FDA-1088."

Topic	S. 1082	H.R. 2900
Advertisements: Civil penalties	S. 1082 Section 519; H.R. 2900 Section 902(a). Amends FFDCA Section 303 to establish civil penalties for the sponsor of a drug or biologic who disseminates a DTC advertisement that is false or misleading.	
	Authorizes a civil monetary penalty not to exceed $150,000 for the first violation in any 3-year period, and not to exceed $300,000 for each subsequent violation in any 3-year period.	Authorizes a civil monetary penalty not to exceed $250,000 for the first violation in any 3-year period, and not to exceed $500,000 for each subsequent violation in any 3-year period.
		No other civil monetary penalties in this act shall apply to a violation regarding DTC advertising.
	Repeated dissemination of the same or similar advertisement prior to the receipt of a written notice shall be considered one violation.	
		After such notification, all violations under this paragraph occurring in a single day shall be considered one violation.
	Specifies procedures, after providing written notice and opportunity for a hearing, regarding reviews, subpoenas, modifications, and judicial review. (Generally equivalent in S. 1082 and H.R. 2900.)	
	If an applicant fails to pay an assessed civil penalty, authorizes the Attorney General to recover that amount plus interest.	
		Requires the Secretary to report annually to the Congress on DTC advertising and its ability to communicate to subsets of the general population, and establish a permanent advisory committee with respect to the report.
Enforcement: Misbranding	Included as *misbranding* the failure to comply with certain requirements.	
	Applies to REMS requirements regarding a labeling change or advertising.	Applies to REMS requirements regarding assessments, additional elements included, or a restriction on distribution or use.
		Applies to non-REMS requirements relating to postmarket studies and clinical trials or labeling.

Topic	S. 1082	H.R. 2900
Enforcement: Civil penalties	S. 1082 Section 203(b) — for FFDCA Section 303(f): Makes an applicant who knowingly fails to comply with a REMS requirement subject to a civil money penalty between $15,000 and $250,000 per violation, and not to exceed $1 million for all such violations adjudicated in a single proceeding.	H.R. 2900 Section 902(b) — for FFDCA Section 303: Makes an applicant who violates a REMS requirement or a requirement regarding postmarket studies or clinical trials or labeling subject to a civil monetary penalty of not more than $250,000 per violation, and not to exceed $1 million for all such violations adjudicated in a single proceeding.
		If a violation continues after the Secretary provides notice of such violation to the applicant, authorizes the Secretary to impose a civil penalty of not more than $10 million per violation, and not to exceed $50 million for all such violations adjudicated in a single proceeding.
		For a violation that is continuing in nature and poses a substantial threat to the public health, authorizes the Secretary to impose a civil penalty not to exceed $1 million for each day that such person is in violation.
Regulation of biological products	Amends PHA Section 351 to *permit* an applicant for a license to submit a REMS as part of the application.	Amends PHA Section 351 to *require* an applicant for a license to be subject to FFDCA Section 505(p) — Risk Evaluation and Mitigation Strategy.
No effect on withdrawal or suspension of approval	Amends FFDCA Section 505(e), adding that the Secretary may withdraw the approval of an application or suspend the approval of an application without first ordering the applicant to submit an assessment of the approved REMS.	
Benefit-risk assessments		Requires that, within a year of enactment, the FDA Commissioner submit to Congress a report on how best to *communicate to the public* the risks and benefits of new drugs and the role of the REMS in assessing such risks and benefits. As part of such study, the Commissioner shall consider the possibility of including in the labeling and any DTC advertisements of a newly approved drug or indication a *unique symbol* indicating the newly approved status of the drug or indication for a period after approval.

Topic	S. 1082	H.R. 2900
Resources	Adds to the list of activities for which user fee revenue can be used to include the reviewing, implementing, and ensuring compliance with REMS.	*Note: A similar provision appears in Title I (Prescription Drug User Fees) of H.R. 2900.*
	Amends FFDCA Section 736 to increase by $225 million the total revenue amounts determined for FY2008 through FY2012.	*Note: A similar provision appears in Title I (Prescription Drug User Fees) of H.R. 2900.*
Information technology (IT)	Requires that the Secretary submit to the Senate HELP and Appropriations Committees, and the House Energy and Commerce and Appropriations Committees, a strategic plan on information technology. Requires that elements of the plan: include an assessment of infrastructure needed by FDA to comply with requirements; achieve interoperability within FDA and with product application sponsors; use electronic health records; implement a routine active surveillance; communicate drug safety information to health care providers; and provide an assessment of the extent to which the infrastructure is sufficient, a plan for enhancing IT assets, and an assessment of additional resources needed.	
Postmarket drug safety information for patients and providers	Requires that the Secretary, within one year of enactment, develop and maintain an Internet website with an extensive range of drug safety information, including summaries of surveillance data, and documents from drug approval and biologics licensing applications such as a summary of conclusions from all reviewing disciplines and staff disagreements and recommendations.	

[illegible]	S. 1082	HR. 2900
Public access to action packages for approval	For drugs and biologics, requires the Secretary to publish on the FDA website, within 30 days of approval, the entire Action Package; and to publish, within 48 hours of a drug's approval, a summary review that documents (without disclosing trade secrets or confidential information) conclusions from all reviewing disciplines, noting critical issues and disagreements with the applicant and how they were resolved, recommendation for action and an explanation of any nonconcurrence with review conclusions; a separate review, if applicable, from a nonconcurring supervisor; and identification (with consent) of FDA participants in the decision. Scientific review shall not be altered by management or review once final; disagreements with major conclusions shall be documented in a separate review or in an addendum.	
Risk communication	Requires the Secretary to establish an Advisory Committee on Risk Communication. Requires that the Secretary partner with nongovernmental groups to develop robust and multifaceted systems for communication to health care providers about emerging postmarket drug risks.	
Referral to advisory committee	Requires that the Secretary, before approving a drug that includes a new active ingredient, refer the drug to an FDA advisory committee. Referral may be delayed up to one year postapproval in specified situations relating to therapeutic results or public health.	
Response to IOM 2006 report	Requires that the Secretary submit a report, within one year, responding to the recommendations in the IOM 2006 report *The Future of Drug Safety*, to include an assessment of FDA's implementation of REMS requirements.	
Active surveillance and assessment	Requires the Secretary to establish public-private partnerships to develop a postmarket risk identification and analysis system using electronic databases. **Note:** The timetables and order of activities vary between the bills.	

Topic	S. 1082	H.R. 2900
Prohibition against food to which drugs or biological products have been added		(H.R. 2900, Section 909) Makes a prohibited act (under FFDCA Section 301, and therefore subject to FFDCA penalties), the introduction of drugs or biologics that are either FDA approved/licensed, or for which substantial clinical investigations have been instituted and made public, unless: (1) the drug or biologic is marketed in food before FDA approval/licensure and before clinical investigations are instituted, or (2) the Secretary issues a regulation, after notice and comment, approving its addition to food.
Effective dates	User fee for review of drug advertising begins October 1, 2007. All other provisions in Subtitle A of Title II begin 180 days after enactment.	All provisions in Title IX begin 180 days after enactment.

Table 8. Antibiotic Drugs

Current Law: The FDA regulates antibiotics as drugs, under FFDCA §505. Orphan drugs, which may be antibiotics, are those that affect less than 200,000 persons in the United States, or affect more than 200,000 persons if there is no reasonable expectation that the cost of developing and making the drug available in the United States will be recovered from sales in the United States. PDUFA application fees do not apply to orphan drugs. The Secretary may encourage the development of orphan drugs by awarding grants and contracts, and may, in certain circumstances, ensure the drugs' continued availability by issuing an approval to a second party within the usual period of market exclusivity.

Major Differences Between Bills: H.R. 2900 would require the Secretary to issue guidance for the conduct of clinical trials of antibiotic drugs, and require the Secretary to convene a public meeting regarding orphan antibiotic products. It would also authorize appropriations of $30 million for each of the next five fiscal years for grants and contracts to develop orphan drugs. S. 1082 would consider antibiotics as orphan products and authorize $35 million for each of those fiscal years. The Senate bill includes other provisions regarding antibiotic access and innovation; one would provide incentives (extended marketing exclusivity) for the development of certain antibiotics.

Topic	S. 1082	H.R. 2900
Location	Title II. Subtitle F, Antibiotic Access and Innovation	Title IX
Law Amended	Sections in Chapter V, Subchapter A of the FFDCA (as noted), as amended by this act.	
Incentives for Development	§ 261. Amends § 505 of the FFDCA (21 U.S.C. § 355), as amended by this act. Makes certain antibiotic drugs eligible for market exclusivity if an application for marketing is submitted after enactment of this act for an antibiotic drug that was approved by the Secretary before November 21, 1997; or was the subject of one or more applications received by the Secretary before November 21, 1997, none of which was approved.	No comparable provision.
Orphan Drugs	§ 262 in S. 1082; § 911 in H.R. 2900. Requires the FDA Commissioner to convene a public meeting and issue guidance, if appropriate, regarding whether certain infectious diseases may be designated as rare diseases, making drug development for treating such diseases eligible for assistance pursuant to the Orphan Drug Act (21 U.S.C. § 360cc).	
	Reauthorizes grants and contracts for orphan drugs (21 U.S.C. § 360cc), including authority for such sums as already have been appropriated for FY2007, and $35 million for each of FY2008 through FY2012.	Reauthorizes grants and contracts for orphan drugs (21 U.S.C. § 360cc), authorizing the appropriation of $30 million for each of FY2008 through FY2012.

Topic	S. 1082	H.R. 2900
Clinically Susceptible Concentrations	§ 263. The Secretary, through the FDA Commissioner, shall identify, and periodically update and publish, "clinically susceptible concentrations" of antimicrobial drugs.	No comparable provision.
Exclusivity of Certain Drugs Containing Single Enantiomers	§ 264. Amends § 505 of the FFDCA [21 U.S. C. 355], as amended by this subtitle, adding a new provision allowing an applicant for a non-racemic drug containing, as an active ingredient a single enantiomer that is contained in a racemic drug approved in another application, to elect to have the single enantiomer considered the same active ingredient as that contained in the approved racemic drug, under certain circumstances.	No comparable provision.
GAO Report	§ 265. Requires the Comptroller General, by January 1, 2012, to report to Congress regarding the effect of provisions in this subtitle in encouraging the development of new antibiotics and other drugs; and preventing or delaying timely generic drug entry into the market.	No comparable provision.
Clinical Trial Guidance for Antibiotic Drugs	No comparable provision.	§ 908. Amends Chapter V of the FFDCA [21 U.S.C. § 351 et seq.], adding a new § 511. Requires the Secretary, within one year of enactment, to issue guidance for the conduct of clinical trials with respect to antibiotic drugs, and to review and update such guidance within five years of enactment.

Table 9. Clinical Trials Databases

Current Law: Registration is currently required for clinical trials of drugs (but not biologics or medical devices) intended to treat serious or life-threatening diseases and conditions (42 U.S.C. 282). Trials are now registered at *clinicaltrials.gov*.

Major Differences Between Bills: H.R. 2900 provides instructions for the immediate creation of a database containing clinical trial results; S. 1082 would require the Secretary to create a database via rulemaking. H.R. 2900 contains more requirements than S. 1082 for when a principal investigator may serve as a *responsible party*, and for registry submissions. It also links the definition of *completion date* to the collection of data relevant to primary and secondary outcomes, and would require registry updates every six months. S. 1082 exempts newly created pediatric postmarket surveillance clinical trials from registry requirements, and allows for the voluntary registration of clinical trials that are not required to be submitted. S. 1082 specifies more criteria than does H.R. 2900 by which the registry must be searchable, specifies a timeline by which the NIH Director must make registry information public, and would require the registry to link to certain public clinical trial results information.

CRS Products: CRS Report RL32832, *Clinical Trials Reporting and Publication*, by Erin D. Williams.

Topic	S. 1082	H.R. 2900
Location	Title II, Subtitle C — Clinical Trials	Title VIII - Clinical Trial Databases
Law Amended	FFDCA Section 505(i) (21 U.S.C. 355(I)).	
	PHSA Section 402 (42 U.S.C. 282). FFDCA Sections 301 (21 U.S.C. 331); 303(f) (21 U.S.C. 333(f)); 505(b) (21 U.S.C. 355(b)); 510(k) (21 U.S.C. 360(k)); 515(c) (21 U.S.C. 360e(c); and 520(m)(2) (21 U.S.C. 360j(2)).	PHSA Title IV (42 U.S.C. 281, et seq.). FFDCA Sections 505(d) (21 U.S.C. 355(d)); 520(g)(2) (21 U.S.C. 360j(g)(2)); 510 (21 U.S.C. 360); and 515(d) (21 U.S.C. 360e(d)).
Registry and/or Results Database Required	Expands the registry and includes links to certain results. Results database to be created by HHS Secretary rulemaking following recommendations to be made in NIH Director's report about best, validated method of making trial results publicly available.	Expands the registry and establishes a results database.
Product Types	Drugs, devices, and biologics.	

Topic	S. 1082	HR. 2900
Public Access	Yes, via Internet.	
	REGISTRY: Internet posting and Freedom of Information Act (FOIA) request disclosures limited to terms of the act. Secretary promulgates regulations that notice of posting be part of informed consent.	BOTH (i.e., Registry and Results Database): FOIA request disclosures not available for results for which the principal investigator is seeking publication. Old versions of updated postings remain available, with trackable changes the public can see.
Location of Databases	National Library of Medicine at NIH	
		REGISTRY: Either supplants or builds on *clinicaltrials.gov*, whichever is more efficient.
Links Registry and Results	REGISTRY: Entries link to certain existing results.	BOTH: Corresponding registry and results database entries link to one another.
Who Submits Information	Responsible party (RP).	
	REGISTRY: RP is sponsor. If no sponsor exists, RP is grantee, contractor or awardee of federal funding. If designated by sponsor, grantee, contractor or awardee, RP is principal investigator (PI).	BOTH: RP is primary sponsor as defined by World Health Organization. RP may be principal investigator (PI) if designated by sponsor and if PI is responsible for conducting the trial, has access to and control over data, has the right to publish trial results, and has the authority to meet the RP responsibilities.
Who Receives Information	NIH Director	

Topic	S. 1082	H.R. 2900
Timing of Submission	REGISTRY: -Initially: not later than 21 days after the first patient is enrolled. -Change in enrollment status: not later than 30 days after change. -Completion of trial: not later than 30 days after the last patient enrolled in the clinical trial has completed his or her last medical visit, whether the clinical trial conducted according to the prespecified protocol or plan was terminated (extensions possible).	REGISTRY: -Initially: not later than 14 days after first patient is enrolled. -Updates: not less than once every 6 months. -Change in Enrollment Status: not later than 30 days after change. -Notice of trial completion: Not later than 30 days after final collection of data from subjects for primary and secondary outcomes. RESULTS: -Generally: Not later than 1 year after earlier of estimated or actual completion date (extensions possible). -Updates: every 6 months for 10 years from when initial posting was required. -Changes in regulatory status: within 30 days after change.
Timing of Posting	REGISTRY: -Trials of drugs and biological products: within 30 days of submission. -Trials of devices: within 30 days of clearance under Section 510(k) of the FFDCA or approval under Sections 515 or 520(m) of the FFDCA. -Links to trial results (from FDA and NIH information) that form the basis of an efficacy claim or are conducted after the drug or biologic is approved or the device is cleared or approved: not earlier than 30 days after the date of approval or clearance, not later than 30 days after the product becomes publicly available.	REGISTRY: -Not specified (NIH Director ensures the registry information is made publicly available via Internet) except that NIH Director may not make registry information about device trials public until the device is approved or cleared by FDA. RESULTS: (*delays of up to 2 years possible if seeking publication*) -Pre-approval studies: not later than 30 days after approval or issuance of not approvable letter. -Summaries of medical, clinical pharmacology reviews of pre-approval and new use studies: within 90 days of applicable date. -Post-approval studies generally: within 30 days of submission. -Post-approval studies of new uses in which manufacturer is a trial sponsor and certifies it is seeking or will seek approval within 1 year: not later than 30 days after approval, issuance of not approvable letter, or application withdrawal: or 2 years after certification.

Topic	S. 1082	H.R. 2900
Searchable By	REGISTRY: -Indication, using Medical Subject Headers -Enrollment status -Trial sponsor -Safety issue being studied	
	REGISTRY: -Study phase -Age group (including pediatric subpopulations) -Study location -National Clinical Trial number or other identification number	RESULTS: -Indication, using Medical Subject Headers -Status of FDA application -Trial phase -Product name -Each financial sponsor -Safety issue being studied
Trials Included	REGISTRY: -Device trials: prospective study of health outcomes comparing an intervention against a control in human subjects intended to support an application under Section 520 (m) [humanitarian devices] or 515 [premarket approval of devices] or a report under Section 510(k) [device clearance] of the FFDCA; pediatric postmarket surveillance as required under Section 522 of the FFDCA (as amended by the bill). -Drug and biologic trials: a controlled clinical investigation of a product subject to FFDCA Section 505 [drug approval] or PHSA Section 351 [approval of biological products]. -Other trials: voluntary submissions possible.	BOTH: -Drug, device, biologic clinical trials: trials testing a product's safety or effectiveness if conducted in the United States or if the product has FDA approval or is the subject of an application for FDA approval.

Topic	S. 1082	H.R. 2900
Exceptions (trials not included)	REGISTRY: -Device trials: limited studies to gather essential information used to refine the device or design a pivotal trial and that is not intended to determine safety and effectiveness of a device. -Drug and Biologic Trials: Phase I trials.	BOTH: -Pharmacokinetic and toxicity studies: a clinical trial to determine the safety of a use of a drug that is designed solely to detect major toxicities in the drug or to investigate pharmacokinetics, unless the clinical trial is designed to investigate pharmacokinetics in a special population or populations. -Feasibility studies: a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary focus is feasibility.
Registry Data Elements	-World Health Organization's International Clinical Trials Registry Platform data set -City, state, zip code, toll-free number of study -Whether there is expanded access for unapproved drugs and biologics under FFDCA Section 561 [emergency situations, patient access to treatments for serious diseases, treatment uses] -Elements specified by Secretary	
	-Links to results from certain FDA submissions, NIH information (Medline cites and NLM database of product labels), and previously existing databank entries	-Estimated completion date -RP identity and contact information -Restrictions on non-employees' discussion or publication of results

Topic	S. 1082	H.R. 2900
Results Data Elements	None.	-Registry data elements, plus: TECHNICAL SUMMARY: -Each sponsor -Scientific point of contact -Description of patient population -Summary data describing achievement of primary and secondary endpoints, assessment of secondary endpoints, safety information -Information about subjects who quit trial -Restrictions on non-employees' discussion or publication of results -Link to peer reviewed publications -Completion date -FDA adverse regulatory action NONTECHNICAL SUMMARY: -Point of contact -General description of results, trial design changes, and reasons for changes BOTH REPORTS: -Trial purpose -Trial sponsor -General description of results, trial design changes, and reasons for changes NIH Director to include links to Medline citations, NLM database product labels, prior databank entries.

Topic	S. 1082	H.R. 2520
Enforcement and Corrections	-RP ensures submissions not false or misleading. -No federal agency may release research grant funds to noncompliant RPs.	
	REGISTRY: -For applicable trials funded by FDA, NIH, AHRQ, or VA, progress report forms include certification of compliance. Agency heads verify compliance before releasing grant funds to RPs. Secretary consults with other federal agencies to determine whether studies funded by them and conducted under 45 C.F.R. 46 [federal protections for human subjects] merit similar procedures. -Applications or submissions under FFDCA Sections 505, 515, 520(m), or 510(k), or PHSA Section 351 [new drugs, biologics and devices], must have certifications of compliance. -Secretary may impose FFDCA penalties for noncompliance.	BOTH: -Secretary consults with other federal agencies to determine whether studies funded by them and conducted under 45 C.F.R. 46 [federal protections for human subjects] are applicable clinical trials, and to develop procedures to ensure results submission. -NIH Director checks registry to ensure corresponding results are filed. After notice to RP, and opportunity to correct, Director reports noncompliance to federal agencies and Office of Human Research Protections, and posts notice of noncompliance in registry and database. -FDA Commissioner to verify submissions are made for trials in applications under FFDCA Sections 505, 505(i) 515, 520(g), or 510(k), or PHSA Section 351 [new or exempt drugs, biologics and devices]. After 30 days after notice, failure to correct leads to Secretary's refusal to file, approve, or clear application. -Secretary to review documents to ensure they are non-promotional, not false or misleading. 30 days after notice of noncompliance, penalties may apply. -Secretary may impose FFDCA penalties for noncompliance, including civil monetary penalties created by the act (not more than $10,000/day, and not more than $15,000 for all violations of an individual or nonprofit adjudicated in a single proceeding).
Required Studies or Reports	RESULTS: NIH Director conducts a study to determine the best, validated methods of making trial results public after the approval of a drug that is the subject of an applicable drug trial. Director submits findings to HHS Secretary within 18 months of initiating study.	BOTH: Not later than 1 year after enactment, Comptroller General submits a report to Congress on a study to determine whether information in the registry and database is considered promotional and to evaluate the implementation of the database.
Authorized Appropriations	Authorizes appropriations of $10,000,000 each fiscal year.	

Topic	S. 1082	H.R. 2900
Preemption	No state or political subdivision of a state may require or effect registration of trials or results.	
Safe Harbor	Compliant submissions shall not be considered (1) by Secretary as evidence of a new intended use different from labeling, or (2) as FFDCA labeling, adulteration, or misbranding.	
Effective Dates	REGISTRY: -Generally: October 1, 2007 -Regulations become effective 90 days after HHS Secretary's issuance of final rule. (Final rule issued pursuant to Act to be issued not later than 18 months after Act's enactment, and after notice and comment.) -Funding restrictions take effect 210 days after regulations' effective date.	BOTH: -Databases established not later than 1 year after enactment.

Table 10. Conflicts of Interest

Current Law: Current law generally requires that FDA advisory committee members be free from conflicts of interest, but allows for exceptions to that rule under specific circumstances. Under FDA's current approach, a conflict of interest may require a potential committee member to disclose the conflict, refrain from voting, and/or not participate in a committee, depending on the nature of the conflict. (5 U.S.C. Appendix; 21 U.S.C. 355(n);18 U.S.C. chapter 11, §208.)

Major Differences Between Bills: H.R. 2900 would only allow one waiver per meeting of a voting restriction allowable if necessary to provide the committee with essential expertise. H.R. 2900 specifically permits the participation of a non-voting guest expert with financial interest if the Secretary determines that the guest has particular required expertise.

CRS Products: CRS Report RS22691, *FDA Advisory Committee Conflict of Interest Reform Efforts in the 110th Congress*, by Erin D. Williams.

Topic	S. 1082	H.R. 2900
Location	Title II, Subtitle D	Title VII
Law Amended	FFDCA chapter VII, subchapter A (21 U.S.C. 371 et seq.); Section 505(n) (21 U.S.C. 355(n)).	
Advisory Committee	Federal Advisory Committee Act (FACA) committee that provides advice or recommendations to the Secretary regarding the FDA.	
Financial Interest	As defined in 18 U.S.C. 208(a): [A committee member who] participates personally and substantially as a government officer or employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, in a judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which, to his knowledge, he, his spouse, minor child, general partner, organization in which he is serving as officer, director, trustee, general partner or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment, has a financial interest. [Notes: The scope of disqualifying financial interests under 18 U.S.C. 208(a) have been interpreted to include any potential for gain or loss to the employee, which would include interests such as stock ownership (5 C.F.R. 2640.103(b)). Exemptions and waivers apply (18 U.S.C. 208(b)). Penalties apply (18 U.S.C. 216).	

Recruitment	Requires the Secretary to develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups. The Secretary shall seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities. The Secretary shall also take into account the advisory committees with the greatest number of vacancies. Both bills list a number of identical activities that may be included (e.g., advertising at medical and scientific society conferences).	
		The Secretary shall act through the Office of Women's Health, the Office of Orphan Product Development, the Office of Pediatric Therapeutics, and other FDA offices with relevant expertise.
Evaluation	When considering a term appointment to an advisory committee, the Secretary shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual will later require an exemption or waiver under 18 U.S.C. 208(b).	
Guest Participation		An individual with a financial interest with respect to any matter considered by an advisory committee may be allowed to participate in a meeting of an advisory committee as a guest expert if the Secretary determines that the individual has particular expertise required for the meeting. An individual participating as a guest expert may provide information and expert opinion, but shall not participate in the discussion or voting by the members of the advisory committee.
Disclosure of Interests	Prior to a meeting of an advisory committee, each member of the committee shall disclose to the Secretary financial interests in accordance with subsection 18 U.S.C. 208(b).	
Voting Prohibition and Exemption from Prohibition	No member of an advisory committee may vote with respect to any matter considered by the advisory committee if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.	
Waiver	The Secretary may grant a waiver of the voting prohibition if such waiver is necessary to afford the advisory committee essential expertise.	

Waiver Limitations	The Secretary may not grant a waiver (under the newly created section above) for a member of an advisory committee when the member's own scientific work is involved.	
		Secretary shall not grant more than one waiver (under the newly created section above) per committee meeting.
Waiver Disclosure	For waivers granted under the terms of the bill or under 18 U.S.C. 208(b), the Secretary must disclose on the FDA website the type, nature, and magnitude of the pertinent financial interests and the reasons for the Secretary's action. The disclosure would be limited so as not to include information that is not subject to a FOIA request. The Secretary would be required to make the disclosure not less than 15 days prior to an advisory committee meeting, or, in the event that the financial interests became known to the Secretary less than 30 days prior to the meeting, no later than the date of the meeting. Required disclosures would be included in the public record and transcript of each meeting.	
Annual Report	The Secretary must submit annual reports to relevant congressional committees describing advisory committee vacancies, nominees, and the number of nominees willing to serve; the number of conflict-related disclosures per meeting and the percentage of members who did not require such disclosures; the number of times required disclosures occurred less than 30 days in advance of meetings; and how the Secretary plans to reduce the number of vacancies on advisory committees and increase the number of nominations, including those of academicians or practitioners.	
Guidance Review	The Secretary must review and update FDA conflict of interest guidance not less than once every five years.	
Conforming Amendment	Redundant provisions in 21 U.S.C. 355(n) would be deleted. The effect of moving the provisions is that they will apply to all FDA FACA advisory committees, not just those focused on drugs and biologics.	
Effective Date	October 1, 2007	

Table 11. Importation of Prescription Drugs

Current Law: Under current law, it is illegal for anyone to import a prescription drug other than its manufacturer. The law includes provisions for pharmacists and wholesalers to import, but provides that they not become effective until the HHS Secretary certifies that the importation program would be safe and offer cost savings to U.S. consumers. Secretaries in both the Clinton and George W. Bush Administrations have declined to provide that certification.

Major Differences Between Bills: The importation provisions are only in S. 1082.

CRS Products: CRS Report RS22660, *Prescription Drug Importation: How S. 242 / H.R. 380 Would Change Current Law*, and CRS Report RL32511, *Importing Prescription Drugs: Objectives, Options, and Outlook*, both by Susan Thaul.

Topic	S. 1082
Location	Title VIII-Importation of Prescription Drugs
Law Amended	Primarily FFDCA Section 804
General Provisions	Allows commercial and personal-use importation, providing the Secretary first certifies that the drugs to be imported under the program would "pose no additional risk to the public's health and safety;" and "result in a significant reduction in the cost of covered products to the American consumer."
	Creates a detailed set of procedures to address concerns relating to the safety and effectiveness of imported drugs, cost savings to U.S. consumers, and administration of the program.
	Required procedures include registration; monitoring, inspecting, and testing; packaging and labeling; wholesale distribution; Internet pharmacies; exporter and commercial importer fees; and reports.

Table 12. Reagan-Udall Foundation

Current Law: No comparable provision.

Major Differences Between Bills: Provisions in the two bills are nearly identical, with one substantive difference noted in the comparison below. Also, S. 1082 makes reference to provisions becoming effective upon enactment of the *Enhancing Drug Safety and Innovation Act of 2007*, the bill (S. 484) from which the title in S. 1082 is derived.

Topic	S. 1082	H.R. 2900
Location	Title II, Subtitle B (§§ 221, 222)	Title VI
Law Amended	Amends FFDCA Chapters VIII and IX (21 U.S.C. 371 et seq., and 391 et seq.) Creates a new §§ 770, 910.	
		Amends FFDCA, Chapter V, Subchapter E (21 U.S.C. 360bbb et seq.). Creates a new § 566.
Foundation Establishment and Functions	Establishes a nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (The Foundation), to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety. Lists duties of the Foundation, criteria for formation, conduct duties, terms and administrative powers of the Board of Directors, and the Executive Director. Stipulates the roles of federal employees involved in the Foundation's functions.	
Foundation, Duties of the Foundation	Duties of the Foundation include "taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including postapproval, of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics..."	Duties of the Foundation include those listed for S. 1082, and, after "cosmetics," "*including the incorporation of more sensitive and predictive tools and devices to measure safety...*"
Foundation, Incorporation and Nonprofit Status	The *ex officio* members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation. The Foundation shall be considered a corporation under Section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of such section.	

Topic	S. 1082	H.R. 2900
Foundation, Funding	The Executive Director may solicit and accept on behalf of the Foundation, any funds, gifts, grants, devises, or bequests of real or personal property, including from private entities, for the purposes of carrying out the duties of the Foundation. The Executive Director shall ensure that the funds received from the U.S. Treasury are held in separate accounts from funds received from other sources.	
	To carry out certain provisions in this subtitle, from amounts appropriated to the FDA for each fiscal year, the Commissioner shall transfer to the Foundation not less than $500,000 and not more than $1,250,000.	
Foundation, Annual Reports	Recipients of grants, contracts, fellowships, memoranda of understanding, or cooperative agreements from the Foundation shall report to the Foundation regarding their activities on an annual basis.	
	Beginning with FY2009, the Executive Director shall submit to Congress and the FDA Commissioner an annual report on the Foundation's activities	
Location of the Foundation	The Foundation shall, if practicable, be located not more than 20 miles from the District of Columbia.	
Foundation, Activities of the FDA	The FDA Commissioner shall, with respect to the Foundation: receive and assess the required annual reports; and, beginning with FY2009, submit to Congress an annual report summarizing the information provided by the Foundation, and other required information. The provisions of this subchapter shall have no effect on any grant, contract, memorandum of understanding, or cooperative agreement between the FDA and any other entity entered into before, on, or after the date of enactment. § 742(b) of the FFDCA (21 U.S.C. 379l(b)) is amended by adding at the end the following: "Any such fellowships and training programs under this section or under Section 770(d)(2)(A)(ix) may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services."	
Office of the Chief Scientist	A new section in FFDCA requires the Secretary to create an Office of the Chief Scientist within FDA's Office of the Commissioner. (Duties specified).	

Topic	S. 1082	H.R. 2900
Critical Path Public-Private Partnerships		Adds a requirement to FFDCA's general provisions relating to drugs and devices (Title V, Subchapter F), that the Secretary, through the FDA Commissioner, enter into collaborative agreements (Critical Path Public-Private Partnerships) with educational or tax-exempt organizations to implement the FDA Critical Path Initiative by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the acceleration of medical product development, and enhancing medical product safety; and authorizes to be appropriated $5 million for FY2008 and such sums as may be necessary for each of FY2009 through FY2012.

Table 13. Food Safety

Current Law: Most of the provisions below would establish new authorities. Amendments to current law are noted when appropriate. FDA food safety authorities are, in general, found in Title IV of the FFDCA (21 U.S.C. § 341 et seq.), with reference when appropriate to other titles (e.g., Title III, regarding prohibited acts and penalties).

Major Differences Between Bills: H.R. 2900 does not contain provisions on this topic.

CRS Products: CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Geoffrey S. Becker and Donna V. Porter, and CRS Report RS22664, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker.

Topic	S. 1082
Location	Title VI
Law Amended	Generally FFDCA, various sections
Safety of Pet Food	§ 602. Within 18 months, the Secretary, in consultation with other stakeholders, shall by regulation establish processing and ingredient standards for pet foods, animal waste and ingredient definitions, and update nutrition and ingredient labeling of pet food. Within 180 days, the Secretary shall, by regulation, establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. The Secretary shall, in establishing such system, use surveillance and monitoring mechanisms similar to, or in coordination with, those used by CDC, consulting with relevant professional organizations, and working with existing notification networks, to inform veterinarians and others during a recall of pet food.
Recall Communication	§ 603. During an ongoing recall of human or pet food, the Secretary shall work with relevant stakeholders to collect and aggregate pertinent information through existing networks of communication, including electronic forms, and post information regarding the recall on FDA's website, in an easily accessible form.

Topic	S. 1082
State and Federal Cooperation	§ 604. The Secretary shall work with the states on activities and programs that assist in improving the safety of fresh and processed produce, to facilitate coordination and cost-effectiveness. The Secretary shall encourage states to strengthen their food safety programs, especially for retail commercial food establishments, and establish procedures and requirements for ensuring that processed produce is not unsafe for human consumption. The Secretary may provide assistance to states in implementing their food safety programs in the following areas: advisory, technical, training, laboratory and financial. The Secretary may under an agreement use, on a reimbursable basis, the personnel, services and facilities of the agency to assist states.
Adulterated Food Registry and Reporting Requirements	§ 605. Amends Title IV of the FFDCA, creating a new § 417, requiring the Secretary, within 6 months, to establish an adulterated food registry within FDA, to which reportable adulterated food cases may be submitted via electronic portal, by public health officials, importers, persons responsible for producing or marketing food, or consumers. The Secretary shall review and determine the validity of information submitted, for the purposes of identifying adulterated food, and exercising other existing food safety authorities to protect the public. The Secretary shall issue an alert, if a food has been associated with repeated and separate outbreaks of illness or incidents of adulteration, or is a reportable adulterated food. Such an alert may apply to a particular food, producer, shipper, growing area or country, where applicable. If a food producer or importer suspects that a food is adulterated, he is required within five days to determine if it is a reportable adulterated food, and if such determination is made, to, within two days, notify responsible parties in the food supply to and from which it was transferred. That individual is then required to notify the FDA within two days through the electronic system, unless the determination of adulteration was detected prior to any transfer of the food which was destroyed, making a report to FDA unnecessary. The provisions outline the data elements required for reporting to FDA for the registry. Records must be maintained and available for inspection, if needed. The Secretary shall immediately notify the Secretary of Homeland Security if he suspects such food may have been deliberately adulterated. Amends § 301 of the FFDCA to prohibit: failure to provide a report, or the falsification of a report, for a food considered to be adulterated. The Secretary shall, within 180 days, promulgate regulations that establish standards and thresholds by which importers and producers are required, and consumers allowed, to report instances of suspected reportable adulterated food to FDA for the registry. Requirements in this section become effective in 6 months.
Sense of the Senate	§ 606. The section addresses congressional responsibility to provide FDA with additional resources, authorities, direction, and inspectors to safeguard the U.S. food supply. It directs that the Secretary should prioritize efforts to reach agreements with U.S. trading partners on food safety, and the Senate should work to develop a comprehensive response to the food safety issue.
Report to Congress Regarding Imported Foods	§ 607. The Secretary shall submit to the relevant congressional committees, annually, a report that includes the number and amount of imported food products regulated by FDA, aggregated by country and type of food; the number of FDA inspectors of imported foods and number of inspections performed on those products; and aggregated date on the findings of those inspections, including violations and enforcement actions taken as a result.

Topic	S. 1082
Rule of Construction	§ 608. Nothing in this title affects the regulation or the adverse event reporting system for dietary supplements created under the Dietary Supplement Health and Education Act of 1994 or the Dietary Supplement and Nonprescription Drug Consumer Protection Act.
Authorization of Appropriations	§ 609. There are authorized to be appropriated to carry out this title (and the amendments made by this title) such sums as may be necessary.

Table 14. Domestic Pet Turtle Market Access

Current Law: Pursuant to regulations at 21 C.F.R. 1240.62, viable turtle (defined) eggs and live turtles with a carapace (shell) length of less than 4 inches shall not be sold, held for sale, or offered for any other type of commercial or public distribution. FDA may humanely destroy eggs or turtles found in violation of this regulation. An appeals procedure is described. Persons in violation of this regulation shall be subject to a fine of not more than $1,000 or imprisonment for not more than 1 year, or both, for each violation. The FDA Commissioner may amend this regulation upon his own initiative or in response to a petition. Certain exceptions are made, including sale for scientific, educational, or exhibitional purposes. The provision is administered by FDA's Center for Veterinary Medicine (CVM).

Major Differences Between Bills: H.R. 2900 does not contain provisions on this topic.

Topic	S. 1082
Location	Title VII
Law amended	Not stated. Authority for the current prohibition is based in Public Health Service Act Sections 215, 311, 361 and 368. (42 U.S.C. 216, 243, 264 and 271.) [General authorities for disease control.]
Sale of Baby Turtles	The FDA shall not restrict the sale by a turtle farmer, wholesaler, or commercial retail seller of a turtle that is less than 10.2 centimeters in diameter (approx. 4 inches), if the seller meets the requirements of a state or territorial program that licenses the seller; requires veterinary certification of sanitization; said sanitization includes a proven non-antibiotic method to make the turtle salmonella-free; and buyers are provided with information regarding safe handling of the turtle with respect to future disease risks.
FDA Review of State Protections	The FDA Commissioner may, after providing an opportunity for the affected state to respond, restrict the sale of a turtle only if the Secretary determines that the actual implementation of state health protections described in this title is insufficient to protect consumers against infectious diseases acquired from such turtle at the time of sale.

Table 15. Other Provisions

Current Law: Most of the provisions below would establish new authorities. Amendments to current law are noted when appropriate. **Major Differences Between Bills:** With two exceptions, beginning on page 60, these provisions are found only in S. 1082.

Topic	S. 1082
Location	Title II Subtitle E-Other Drug Safety Provisions; and Title V-Other Provisions
Law Amended	(Noted when applicable)
Authorized Generic Drugs	Sec. 251. Would amend FFDCA Section 505 to require that the FDA Commissioner (within nine months of enactment) publish on the FDA website a list of all authorized generic drugs; update the list quarterly; and notify relevant federal agencies of those updates. Defines, for this section, an authorized generic drug as one that had previously been approved under Section 505(c) and then "marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug."
Medical Marijuana	Sec. 252. Requires that the Secretary require that state-legalized medical marijuana be subject to the full FDA regulatory requirements, including a risk evaluation and mitigation strategy (REMS) and all other requirements and penalties of the FFDCA (21 U.S.C. 301 et seq.) regarding safe and effective reviews, approval, sale, marketing, and use of pharmaceuticals
Scientific Articles Published by FDA Employees	§ 501. Amends Subchapter A of chapter VII of the FFDCA, as amended by Section 241. The Secretary, through the FDA Commissioner, shall establish and make publicly available clear written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles. Requires employee to submit articles to appropriate supervisory FDA personnel for review not less than 30 days prior to publication or presentation. Requires supervisory FDA personnel to provide written clearance, which may include conditions, within 30 days of submission. If supervisory personnel do not provide written clearance within 30 days, employee may submit work for publication or presentation, with disclaimer.
Technical Amendments to the Public Health Service Act	§ 502. Miscellaneous technical amendments.

Topic	S. 1082
Severability	§ 503. If any provision of this act, or any amendment made by this act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this act, the amendments made by this act, and the application of the provisions of such to any person or circumstances shall not be affected thereby.
Follow-on Biologics	§ 504. Includes a Sense of the Senate statement regarding providing FDA with appropriate authority to review follow-on biologics.
Treatments for Tropical Diseases: Priority Reviews	§ 505. Amends Subchapter A of chapter V of the FFDCA, adding a new § 524. The Secretary shall award a priority review voucher to the sponsor of a tropical disease product (defined) upon approval by the Secretary of such product (after the enactment of this provision). The voucher, which is transferrable, would entitle the bearer to priority review of a new drug application, submitted under FFDCA § 505(b)(1), after the date of approval of the tropical disease product. The Secretary shall establish a user fee program to support priority reviews.
Pesticide Residue Monitoring	§ 507. Requires annual online publication of FDA report on pesticide residue monitoring with information and analysis, identifying products or countries that require special attention and additional study. The Ginseng Dietary Supplements Special Survey is to be included, along with the relative number of domestic and import shipment samples and a description of commodities improperly imported as another commodity. Reports for FY2004 through FY2006 are to be combined into a single report by June 1, 2008, with future reports completed by June 1 each year. The Commissioner of FDA, the Administrator of the Food Safety and Inspection Service, the Department of Commerce, and the head of the Agricultural Marketing Service shall enter into a memorandum of understanding to permit inclusion, in the reports required above, of data relating to testing carried out by the Food Safety and Inspection Service and the Agricultural Marketing Service on meat, poultry, eggs, and certain raw agricultural products.
Head Start Act Amendment	§ 508. Amends the Head Start Act [42 U.S.C.§§ 9831 et seq.] by adding a new § 657A. Requires a Head Start agency to obtain written parental consent before administration of any nonemergency intrusive physical examination (defined) of a child in connection with participation in a program under this subchapter.
Safety of Food Additives	§ 509. Within 90 days of enactment, FDA is required to issue a report on whether substances used to preserve the appearance of meat create health hazards or mislead consumers.
Genetic Test Safety and Quality	§ 510. Requires the Secretary, within 30 days of enactment, to enter into a contract with the Institute of Medicine to study and assess the overall safety and quality of genetic tests, and prepare, within one year of contract award, a report that includes recommendations to improve federal oversight and regulation of genetic tests.
Orphan Disease Treatment in Children	§ 511. Includes the finding that FDA approved drugs are often not approved for treatment of pediatric orphan diseases, and a Sense of the Senate statement that FDA should enter into a contract with the Institute of Medicine to study the problem.

Topic	S. 1082
Color Additive Certification Reports	§ 512. Amends § 721 of the FFDCA. Requires FDA to submit a report to Congress, within 90 days of the close of each fiscal year, that describes the number of batches of color additives approved, the average time for approval and quantifiable goals for improving laboratory efficiencies. A second report on the financial status is required, within 120 days of the end of the fiscal year, that includes all fees and expenses of the program, the balance of funds available, and the anticipated costs during the next fiscal year, of the color additive certification program.
Imported Food Inspection	§ 513. Prohibits the importation of food from a foreign food facility, registered with FDA, that refuses to permit inspection, or unduly delays access to that facility by U.S. inspectors.
Seafood Inspections	§ 515. Authorizes the Secretary to enhance FDA's aquaculture and seafood inspection regime consistent with international agreements and U.S. law. Requires a report to Congress, within 90 days of enactment, that describes the specifics of the inspection program, the feasibility of developing traceability systems for catfish and seafood products to processing plants (foreign and domestic) and an assessment of the risks associated with contaminants and banned substances. The provision allows partnership agreements with the states to implement the inspection program for imported products, and authorizes the appropriation of such sums as are necessary to implement the program.
Sense of the Senate re: Patent Infringements	§ 516. Includes findings regarding the problem of patent infringement, statement urging the United States Trade Representative to use all the tools at his or her disposal to address violations and other concerns with intellectual property.
Genetically Engineered Seafood Products	§ 517. The FDA Commissioner shall consult with the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with any genetically engineered seafood products, including the impact on wild fish stocks.
Report on the Marketing of Certain Crustaceans	§ 518. Within 30 days of enactment, the Secretary, in consultation with the Secretary of Commerce, shall submit to the appropriate congressional committees a report on the differences between certain species of lobster, which is to describe differences in consumer perception, including taste, quality and value of these species.
Report re: Indoor Tanning devices and Skin Cancer	§ 520. Requires the Secretary, acting through the FDA Commissioner, to: make certain determinations regarding the labeling of indoor tanning devices; conduct consumer testing: hold public hearings; and report to Congress within one year of enactment.

Topic	S. 1082	H.R. 2900
Anticounterfeiting Technologies	§ 514. Requires (within 18 months of enactment) that the packaging of any prescription drug incorporate a standardized numerical identifier unique to each package, applied at the point of manufacturing and repackaging. Requires (within 24 months for the 50 prescription drugs with the highest dollar volume of U.S. sales in 2007, and within 30 months for all other prescription drugs) that packaging incorporate overt optically variable counterfeit-resistant technologies, or other technologies with comparable security function.	§ 910 in H.R. 2900. Requires the Secretary (in consultation with other federal agencies, including the Drug Enforcement Administration, the Department of Homeland Security, and the Department of Commerce) to develop and prioritize standards and evaluate technologies to secure the distribution system against prescription drugs that are counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired. Requires the Secretary: to address radiofrequency identification technology, nanotechnology, encryption technologies, and other track-and-trace technologies; to expand and enhance the resources and facilities of the FDA Office of Regulatory Affairs to protect the prescription drug distribution system; and to undertake enhanced and joint enforcement activities with other federal agencies and state officials, and establish regional capabilities for validation and inspection.

Topic	S. 1082	H.R. 2900
Citizen Petition, General Provisions (regarding the approval of generic applications or abbreviated new drug applications (ANDAs)	S. 1082, Sec. 506; H.R. 2900, Sec. 912. Prohibits the Secretary from delaying the review or approval of generic or abbreviated new drug applications on the basis of a petition that seeks to have the Secretary take, or refrain from taking, actions relating to the application's approval. Prohibition is excepted when the Secretary determines that a delay is necessary to protect the public health.	
	The Secretary must make such public health determination *not later than 25 business days* after the submission of the petition.	There is *no time limit* for the Secretary's determination.
	The Secretary must post a detailed statement on the FDA website, providing the reasoning for the determination on the FDA website, within 5 days after the determination. (Requirements specified).	
		If the Secretary determines that the primary purpose of submitting the petition was to delay approval, the Secretary can deny the petition at any point.
		If the 180-day marketing exclusivity would be forfeited because the applicant failed to obtain tentative approval status within 30 months (according to (j)(5)(D)(i)(IV)), the 30-month period is extended by the time equal to the time from when the Secretary received the petition and when a final agency action on the petition occurred.
Citizen Petition, Notice to Applicant	The Secretary must give notice of the delay to the applicant...	
	... within 10 days of the determination. Within this time the Secretary must also provide the applicant *an opportunity to discuss* the determination with appropriate staff as determined by the Commissioner.	... in a *written explanation*. There is *no time limit* for providing the explanation. There is *no mandatory opportunity to discuss* the determination.

Topic	S. 1082	H.R. 2900
Citizen Petition, Final Agency Action	The Secretary must take final agency action not later than 180 days from when the petition was submitted...	
	... *but the Secretary may delay final action if necessary to protect the public health.*	... and no extension is possible.
Citizen Petition, Relationship of Petition Review and Drug Approval	The Secretary cannot delay approval of such applications *while a petition* that seeks to have the Secretary take, or refrain from taking, actions relating to the application's approval *is reviewed and considered.*	The *petition* must be *considered separate and apart from the review* and approval of the application.
Citizen Petition, Verifications	Specified certifications must be submitted with citizen petitions, verifying their truthfulness under penalty of perjury...	
	... without which, the Secretary *must not accept* a petition for review. *Specifies what information must be filled in the blanks (i.e. date and signature) of the certification.* The Secretary must not accept for review any *supplemental information or comments* on a petition unless they are in writing, accompanied by certifications under penalty of perjury.	... without which the Secretary *may not consider* the petition for review. *One required certification states "I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me."*
Citizen Petition, Civil Action		If a civil action is filed with respect to any issue raised in a petition before a final agency action, the court must dismiss the action for failure to exhaust administrative remedies.

Topic	S. 1082	H.R. 2900
Citizen Petition, Annual Report	Requires the Secretary to provide an annual report to Congress that includes the number of generic applications and ANDAs approved during the preceding 12 months: the number of such applications whose effective dates were delayed by petitions during that period: and the number of days by which applications were delayed.	
	The report must also contain: the number of petitions submitted during that period; the number of application approvals delayed for public health reasons while petitions were reviewed (according to (1)(A)(iii)); and the number of days of the delay.	
Citizen Petition. Exceptions	The subsection does not apply to a petition that is made by the sponsor of the application and that seeks only to have the Secretary take or refrain from taking action on that application.	
		The subsection does not apply to *a petition that relates solely to the timing of the approval of an application pursuant to FDCA § 505(j)(5)(B)(iv).*
Citizen Petition. Reports	The Office of Inspector General must issue a report evaluating evidence of the compliance of the FDA with the requirement that the consideration of petitions that do not raise public health concerns remain separate and apart from the review and approval of a generic drug application or ANDA.	The Secretary must submit a report to Congress on ways to encourage the early submission of petitions under the provisions added by § 505(q), as added by H.R. 2900, § 912(a).
Citizen Petition, Existing Regulations	No similar provision.	Existing regulations regarding citizen petitions, and administrative stays of action (21 C.F.R. §§ 10.30, 10.35), or any successor regulations, apply in addition to this section's requirements.
Citizen Petition. Definition	For purposes of the subsection, "petition" includes any request to the Secretary for an action (such as a delay in the effective date of the application). The request need not be characterized as a petition.	

Note: This table was created with assistance from Vanessa Burrows, Legislative Attorney, CRS American Law Division.