timeframe or the information is incomplete, the application will be placed on hold (with a major deficiency letter or AI letter) until the information is received.

FDA will develop a guidance document that incorporates these general principles and should make them operational within the review processes for 510(k)s, PMAs, and PMA supplements. FDA will use this detailed interactive review summary as the basis for a guidance document which FDA will issue as a ''final'' guidance 6 months from the date an agreed upon legislative package is sent to Congress or 3 months from the date of enactment, whichever is later.

I. Meetings.

FDA will make every effort to schedule both informal and formal meetings, both before and during the review process, in a timely manner and industry will make every effort to provide timely and relevant information to make the meetings as productive as possible. These meetings include, but are not limited to the following: pre-submission meetings, determination meetings, agreement meetings, and Day-100 meetings (for PMAs).

J. Quarterly performance reports.

The agency will report quarterly its progress toward meeting the quantitative goals described in this letter and will do so in a timely manner. In addition, for all submission types, FDA will track total time (time with FDA plus time with the company) from receipt or filing to final decision for approval, denial, SE, or NSE. FDA will also provide de-identified review performance data for the branch with the shortest average review times and the branch with the longest average review times for 510(k)s, 180-day supplements, and real-time supplements on an annual basis. Finally, in an effort to enhance accountability and transparency, the agency will meet with the industry informally on a semi-annual basis to discuss issues related to performance and expenditures. At that time, the agency will provide a qualitative update on how funding is being used for the device review process, including investments in information technology and training.

K. New commitments.

All agency guidance documents will reflect commitments made in this goals letter, as appropriate. If a guidance document has not been updated, FDA will still act in accordance with the goals letter.

L. Reviewer training.

As resources permit, the agency will apply user fee revenues to support reviewer training that is related to the process for the review of devices, including training to enhance scientific expertise. FDA will provide summary information on the types of training provided to its staff on an annual basis.

M. Guidance document development.

The agency will continue to develop guidance documents to the extent possible without adversely impacting the timeliness of review of MDUFA-related submissions. Each year, FDA will post a list of guidance documents it is considering for development and provide stakeholders an opportunity to provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

N. Imaging devices with contrast agents or radiopharmaceuticals.

FDA will, after consultation with affected parties, develop a guidance document intended to ensure timely and effective review of, and consistent and appropriate postmarket regulation and labeling recommendations for, diagnostic imaging devices used with imaging contrast agents and/or radiopharmaceuticals approved for the same or different indications. Draft guidance will be published by the end of FY 2008, and will be subject to a 90-day public comment period. FDA will issue a final guidance within one year of the close of the public comment period.

O. In vitro diagnostics.

To facilitate the development of in vitro diagnostic (IVD) devices, FDA will continue to explore ways to clarify the regulatory requirements and reduce regulatory burden, as appropriate, by:

1. Issuing new or revised guidance on: (a) the conduct of clinical trials involving deidentified leftover specimens; (b) clinical trial design issues for molecular diagnostic tests; (c) migration studies; (d) Herpes Simplex Virus IVDs; (e) enterovirus IVDs; and (f) influenza testing.

2. Conducting a pilot program to evaluate integrating the 510(k) review and Clinical Laboratory Improvement Amendments (CLIA) waiver review processes for possible increased efficiencies. This pilot will include only voluntary participants from industry, and the 510(k) applications involved in the pilot will not be counted toward the MDUFA performance goals.

3. Considering industry proposals on acceptable CLIA waiver study protocols, developing acceptable protocol designs, and making them available by adding appendices to the CLIA waiver guidance or by posting redacted protocols on the FDA website.

4. Tracking review times for CLIA waiver applications, sharing this information with industry annually and, at the end of year two of MDUFA, evaluating whether CLIA waiver user fees and performance goals should be considered for MDUFA III.

5. Reviewing a list of class I and II low risk IVD devices, to be provided by industry, to determine whether any of them could be exempted from premarket notification, and allowing interested parties to petition for exemptions consistent with section 510(m)(2) of the Federal Food, Drug, and Cosmetic Act (the Act).

6. Performing a review of its pre-IDE program for IVD devices. This review will be conducted during the first year of MDUFA and will focus on specific issues identified by industry that they would like to see addressed by the program review.

P. Transition period.

FDA will meet the performance goals established under MDUFA II beginning October 1, 2007. However, because, beginning October 1, 2007, FDA will be reviewing submissions under MDUFMA I goals and MDUFA II goals at the same time (due to submissions received in FY 2007 but acted upon in FY 2008), FDA will not manage to the MDUFMA I cycle goals for those submissions received in fiscal year 2007. FDA will meet the MDUFMA I decision goals for submissions received in FY07 and will apply the principles of interactive review.

II. Definitions and explanations of terms.

A. FDA Decision.

PMA decisions are approval, approvable, approvable pending GMP inspection, not approvable, withdrawal, and denial. 510(k) decisions are substantially equivalent (SE) or not substantially equivalent (NSE).

Not Approvable decisions will generally not be issued on the first review cycle. The rare cases where a not approvable decision might be issued on the first review cycle would include situations such as (1) the application is complete and there are no outstanding FDA issues, but the data do not demonstrate that the device provides reasonable assurance of safety and effectiveness, or (2) the PMA receives a not approvable recommendation from an advisory panel. Any ''Not Approvable'' decision will be accompanied by the rationale for its issuance.

Submission of an unsolicited major amendment to any original PMA, premarket report, panel-track supplement, or 180-day supplement extends the FDA decision goal date by the number of days equal to 75 percent of the difference between the filing date and the date of receipt of the amendment.

B. Expedited review.

The MDUFA II expedited review performance goals will apply only to devices for which expedited review has been granted in accordance with section 515(d)(5) of the Act.

If in any one fiscal year, the number of submissions granted expedited review equals 10 or more, FDA will be held to the expedited review performance goals for that fiscal year.

If in any one fiscal year, the number of submissions granted expedited review is less than 10, then it is acceptable to combine the submissions for the following year(s) in order to form a cohort of 10 submissions upon which FDA will be held to the performance goals. However, FDA will continue to report performance data on the cohort for each fiscal year.

C. PMA modules.

Action on a PMA module includes accepting the module, request for additional information, receipt of the PMA, and withdrawal of the module.

D. 180-day PMA supplements.

Decisions for 180-day PMA supplements include approval, approvable, approvable pending GMP inspection, and not approvable.

FDA will implement a major deficiency letter process for 180-Day PMA Supplements (similar to that for PMAs).

E. Real-time PMA supplements.

Decisions for real-time PMA supplements include approval, approvable, and not approvable.

PERFORMANCE GOALS FOR THE PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

Mr. KENNEDY. Mr. President, on September 20, 2007, the Senate passed H.R. 3580, the Food and Drug Administration Amendments Act of 2007. Title I of this bill is the reauthorization of the FDA's prescription drug user fee program, and includes the initial authorization for a voluntary user fee program for advisory reviews of direct-to-consumer television advertising.

Performance goals, existing outside of the statute, accompany the reauthorization of the drug user fee program and the authorization of the advisory review user fee program. These goals represent a realistic projection of what the Food and Drug Administration's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research can accomplish with industry cooperation. The Secretary of Health and Human Services forwarded these goals to the chairmen of the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate, in a document with two sections entitled ''PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES'' and ''PERFORMANCE GOALS AND PROCEDURES FOR ADVISORY REVIEW OF DIRECT-TO-CONSUMER TELEVISION ADVERTISING.'' According to Section 101(c) of H.R. 3580, ''the fees authorized by the amendments made in this title will

be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals . . .in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the CONGRESSIONAL RECORD.''

Today I am submitting for the RECORD this document, which was forwarded to the Committee on Health, Education, Labor and Pensions on September 27, 2007, as well as the letter from Secretary Leavitt that accompanied the transmittal of this document.

The agency-industry agreement on prescription drug user fees includes, for each of the 5 fiscal years of the reauthorization, an additional $29,290,000 and 82 full time employees for the postmarket drug safety activities described in the document. These funds are augmented in Title I of H.R. 3580 by an additional $225 million for postmarket drug safety, $25 million for fiscal year 2008, $35 million for fiscal year 2009, $45 million for fiscal year 2009, $55 million for fiscal year 2010, and $65 million for fiscal year 2011. The FDA will use this $225 million to implement the postmarket drug safety programs and authorities set out in Title IX of H.R. 3580.

I ask unanimous consent this material be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

HEALTH AND HUMAN SERVICES,
Washington, DC, September 27, 2007.

EDWARD M. KENNEDY,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR CHAIRMAN KENNEDY: I want to congratulate you for completing action on the FDA Amendments Act, H.R. 3580. As you know, this bill contains the reauthorization of user fees for drugs and devices as well as other key provisions vital to the Food and Drug Administration. We appreciate your support and hard work on this legislation, the commitment of Members of the Committee in working out these measures, and the support shown by the full Senate.

I am including as enclosures to this letter the two commitment documents for the drug and device user fee programs which outline the agreements between the Agency and the industries with regard to application approval timeframes, issuance of guidances, post market program enhancements, and milestones for other activities to be supported by user fees. These documents cover fiscal years 2008 through 2012 and they represent the commitment of the Department and the FDA to carry out the goals under the mutual agreement with the industries.

Thank you again for successful enactment of the FDA Amendments Act. I look forward to working with you as we proceed with the implementation of this legislation.

Sincerely,

MICHAEL O. LEAVITT,
Secretary.

SECTION A: PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2008 THROUGH 2012

The performance goals and procedures of the FDA Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), as agreed to under the reauthorization of the prescription drug user fee program in the [cite statute] are summarized below.

Unless otherwise stated, goals apply to cohorts of each fiscal year (FY).

I. REVIEW PERFORMANCE GOALS

A. NDA/BLA Submissions and Resubmissions

1. Review and act on 90 percent of standard original NDA and BLA submissions within 10 months of receipt.

2. Review and act on 90 percent of priority original NDA and BLA submissions within 6 months of receipt.

3. Review and act on 90 percent of Class 1 resubmitted original applications within 2 months of receipt.

4. Review and act on 90 percent of Class 2 resubmitted original applications within 6 months of receipt.

B. Original Efficacy Supplements

1. Review and act on 90 percent of standard efficacy supplements within 10 months of receipt.

2. Review and act on 90 percent of priority efficacy supplement within 6 months of receipt.

C. Resubmitted Efficacy Supplements

1. Review and act on 90 percent of Class 1 resubmitted efficacy supplements within 2 months of receipt.

2. Review and act on 90 percent of Class 2 resubmitted efficacy supplements within 6 months of receipt.

D. Original Manufacturing Supplements

1. Review and act on 90 percent of manufacturing supplements within 6 months of receipt and review and act on 90 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

E. These review goals are summarized in the following table:

ORIGINAL AND RESUBMITTED NDAs/BLAs AND EFFICACY SUPPLEMENTS

Submission cohort	Standard	Priority
Original Applications	90% in 10 Mo	90% in 6 Mo.
Class 1 Resubmissions	90% in 2 Mo	90% in 2 Mo.
Class 2 Resubmissions	90% In 6 Mo	90% in 6 Mo.
Original Efficacy Supplements.	90% in 10 Mo	90% in 6 Mo.
Class 1 Resubmitted Efficacy Supplements.	90% in 2 Mo	90% in 2 Mo.
Class 2	90% in 6 Mo	90% in 6 Mo.
MANUFACTURING SUPPLEMENTS		
FY 2008–2012	90% in 6 Mo	90% in 4 Mo.

II. NEW MOLECULAR ENTITY (NME) PERFORMANCE GOALS

A. The performance goals for standard and priority original NMEs in each submission cohort will be the same as for all of the original NDAs (including NMEs) in each submission cohort but shall be reported separately.

B. For biological products, for purposes of this performance goal, all original BLAs will be considered to be NMEs.

III. MEETING MANAGEMENT GOALS

A. Responses to Meeting Requests

1. Procedure: Within 14 calendar days of the Agency's receipt of a request from industry for a formal Type A meeting, or within 21 calendar days of the Agency's receipt of a request from industry for a formal Type B or Type C meeting (i.e., a scheduled face-to-face, teleconference, or videoconference), CBER and CDER should notify the requester in writing (letter or fax) of the date, time, and place for the meeting, as well as expected Center participants.

2. Performance Goal: FDA will provide this notification within 14 days for 90% of Type A meeting requests and within 21 days for 90% of Type B and Type C meeting requests.

B. Scheduling Meetings

1. Procedure: The meeting date should reflect the next available date on which all applicable Center personnel are available to attend, consistent with the component's other business; however, the meeting should be scheduled consistent with the type of meeting requested. If the requested date for any of these types of meetings is greater than 30, 60, or 75 calendar days (as appropriate) from the date the request is received by the Agency, the meeting date should be within 14 calendar days of the date requested.

a) Type A Meetings should occur within 30 calendar days of the Agency receipt of the meeting request.

b) Type B Meetings should occur within 60 calendar days of the Agency receipt of the meeting request.

c) Type C Meetings should occur within 75 calendar days of the Agency receipt of the meeting request.

2. Performance goal: 90% of meetings are held within the timeframe.

C. Meeting Minutes

1. Procedure: The Agency will prepare minutes which will be available to the sponsor 30 calendar days after the meeting. The minutes will clearly outline the important agreements, disagreements, issues for further discussion, and action items from the meeting in bulleted form and need not be in great detail.

2. Performance goal: 90% of minutes are issued within 30 calendar days of date of meeting.

D. Conditions

For a meeting to qualify for these performance goals:

1. A written request (letter or fax) should be submitted to the review division; and

2. The letter should provide:

a) A brief statement of the purpose of the meeting;

b) A listing of the specific objectives/outcomes the requester expects from the meeting;

c) A proposed agenda, including estimated times needed for each agenda item;

d) A listing of planned external attendees;

e) A listing of requested participants/disciplines representative(s) from the Center;

f) The approximate time that supporting documentation (i.e., the ''backgrounder'') for the meeting will be sent to the Center (i.e., ''x'' weeks prior to the meeting, but should be received by the Center at least 2 weeks in advance of the scheduled meeting for Type A meetings and at least 1 month in advance of the scheduled meeting for Type B and Type C meetings); and

3. The Agency concurs that the meeting will serve a useful purpose (i.e., it is not premature or clearly unnecessary). However, requests for a ''Type B'' meeting will be honored except in the most unusual circumstances.

Sponsors are encouraged to consult available FDA guidance to obtain further information on recommended meeting procedures.

IV. CLINICAL HOLDS

A. Procedure: The Center should respond to a sponsor's complete response to a clinical hold within 30 days of the Agency's receipt of the submission of such sponsor response.

B. Performance goal: 90% of such responses are provided within 30 calendar days of the Agency's receipt of the sponsor's response.

V. MAJOR DISPUTE RESOLUTION

A. Procedure: For procedural or scientific matters involving the review of human drug applications and supplements (as defined in PDUFA) that cannot be resolved at the signatory authority level (including a request for reconsideration by the signatory authority after reviewing any materials that are planned to be forwarded with an appeal to the next level), the response to appeals of decisions will occur within 30 calendar days of the Center's receipt of the written appeal.

B. Performance goal: 90% of such answers are provided within 30 calendar days of the Center's receipt of the written appeal.

C. Conditions:

1. Sponsors should first try to resolve the procedural or scientific issue at the signatory authority level. If it cannot be resolved at that level, it should be appealed to the next higher organizational level (with a copy to the signatory authority) and then, if necessary, to the next higher organizational level.

2. Responses should be either verbal (followed by a written confirmation within 14 calendar days of the verbal notification) or written and should ordinarily be to either grant or deny the appeal.

3. If the decision is to deny the appeal, the response should include reasons for the denial and any actions the sponsor might take in order to persuade the Agency to reverse its decision.

4. In some cases, further data or further input from others might be needed to reach a decision on the appeal. In these cases, the ''response'' should be the plan for obtaining that information (e.g., requesting further information from the sponsor, scheduling a meeting with the sponsor, scheduling the issue for discussion at the next scheduled available advisory committee).

5. In these cases, once the required information is received by the Agency (including any advice from an advisory committee), the person to whom the appeal was made, again has 30 calendar days from the receipt of the required information in which to either deny or grant the appeal.

6. Again, if the decision is to deny the appeal, the response should include the reasons for the denial and any actions the sponsor might take in order to persuade the Agency to reverse its decision.

7. N.B. If the Agency decides to present the issue to an advisory committee and there are not 30 days before the next scheduled advisory committee, the issue will be presented at the following scheduled committee meeting in order to allow conformance with advisory committee administrative procedures.

VI. SPECIAL PROTOCOL QUESTION ASSESSMENT AND AGREEMENT

A. Procedure: Upon specific request by a sponsor (including specific questions that the sponsor desires to be answered), the Agency will evaluate certain protocols and issues to assess whether the design is adequate to meet scientific and regulatory requirements identified by the sponsor.

1. The sponsor should submit a limited number of specific questions about the protocol design and scientific and regulatory requirements for which the sponsor seeks agreement (e.g., is the dose range in the carcinogenicity study adequate, considering the intended clinical dosage; are the clinical endpoints adequate to support a specific efficacy claim).

2. Within 45 days of Agency receipt of the protocol and specific questions, the Agency will provide a written response to the sponsor that includes a succinct assessment of the protocol and answers to the questions posed by the sponsor. If the Agency does not agree that the protocol design, execution plans, and data analyses are adequate to achieve the goals of the sponsor, the reasons for the disagreement will be explained in the response.

3. Protocols that qualify for this program include: carcinogenicity protocols, stability protocols, and Phase 3 protocols for clinical trials that will form the primary basis of an efficacy claim. (For such Phase 3 protocols to qualify for this comprehensive protocol assessment, the sponsor must have had an end of Phase 2/pre-Phase 3 meeting with the review division so that the division is aware of the developmental context in which the protocol is being reviewed and the questions being answered.)

4. N.B. For products that will be using Subpart E or Subpart H development schemes, the Phase 3 protocols mentioned in this paragraph should be construed to mean those protocols for trials that will form the primary basis of an efficacy claim no matter what phase of drug development in which they happen to be conducted.

5. If a protocol is reviewed under the process outlined above and agreement with the Agency is reached on design, execution, and analyses and if the results of the trial conducted under the protocol substantiate the hypothesis of the protocol, the Agency agrees that the data from the protocol can be used as part of the primary basis for approval of the product. The fundamental agreement here is that having agreed to the design, execution, and analyses proposed in protocols reviewed under this process, the Agency will not later alter its perspective on the issues of design, execution, or analyses unless public health concerns unrecognized at the time of protocol assessment under this process are evident.

B. Performance goal: 90% of special protocols assessments and agreement requests completed and returned to sponsor within timeframes.

C. Reporting: The Agency will track and report the number of original special protocol assessments and resubmissions per original special protocol assessment.

VII. ADDITIONAL PROCEDURES

A. Simplification of Action Letters

To simplify regulatory procedures, CBER and CDER intend to amend their regulations and processes to provide for the issuance of either an ''approval'' (AP) or a ''complete response'' (CR) action letter at the completion of a review cycle for a marketing application.

B. Timing of Sponsor Notification of Deficiencies in Applications

To help expedite the development of drug and biologic products, CBER and CDER intend to submit deficiencies to sponsors in the form of a ''discipline review'' (DR) letter when each discipline has finished its initial review of its section of the pending application.

VIII. ENHANCEMENT AND MODERNIZATION OF THE FDA DRUG SAFETY SYSTEM

FDA will use user fees to enhance and modernize the current U.S. drug safety system. FDA will adopt new scientific approaches, improve the utility of existing tools for the detection, evaluation, prevention, and mitigation of adverse events, and continue to enhance and improve communication and coordination between post-market and pre-market review staff. Enhancements to the post-market drug safety system will improve the public health by increasing patient protection while continuing to enable access to needed medical products. User fees will provide support for 1) preparing and implementing a 5-year plan to modernize drug safety, including improving communication and coordination between the post-market and pre-market review staff, 2) conducting and/or supporting activities designed to modernize the process of pharmaco-vigilance, 3) developing with sponsors, reviewing, and monitoring implementation of risk management plans, and 4) related activities.

A. Development of 5-year plan, and Communications and Technical Interactions

1. The FDA will develop and periodically update a 5-year plan describing activities that will lead to enhancing and modernizing FDA's drug safety activities/system. The activities described in the 5-year plan will include:

a) Assessment of current and new methodologies to maximize the public health benefit associated with collecting adverse event information at various points during the product lifecycle;

b) With input from academia, industry, and others from the general public, identifying epidemiology best practices and developing guidance(s) describing these practices;

c) Expanding CBER/CDER's database acquisition and use for the purposes of targeted post-marketing surveillance and epidemiology;

d) Developing and validating risk management and risk communication tools, including assessing the effectiveness of risk management plan agreements and developing, implementing, and evaluating mechanisms for public communications about the benefits and risks of drugs and biological products;

e) Improving post-market IT systems (e.g., AERS 2, safety tracking system, and opportunities for linked data management);

f) Enhancing and improving communication and coordination between the Office of Surveillance and Epidemiology and the Office of New Drugs in CDER and the Office of Biostatistics and Epidemiology and the pre-market product review Offices in CBER, including activities to assess the impact and value of routinely including post-market review staff on pre-market review teams.

2. The plan will be drafted, published on the FDA website, and updated as follows:

a) FDA will publish a draft of the plan by March 31, 2008. At that time, FDA will solicit and consider comments from the public on the draft plan. The public comment period will be at least 45 calendar days. FDA will complete revisions to the plan and publish the final version no later than December 31, 2008.

b) By the end of FY 09, FDA will conduct an annual assessment of progress against the plan to be published on the FDA website. The report will describe progress on issues outlined in the five year plan. In addition, the report will include FDA efforts to facilitate the interactions between OND/OSE related to the process of evaluating and responding to post-marketing drug safety/adverse event reports.

c) FDA will publish updates to the plan as FDA deems necessary. FDA will publish on the FDA website draft revisions to the plan, solicit comments from the public on those draft revisions, and consider the public comments before completing and publishing updates to the plan.

B. Conduct and support activities designed to modernize the process of pharmaco-vigilance

1. Maximize the Public Health Benefit of Adverse Event (AE) Collection Throughout

the Product Life Cycle: By the end of FY 08, FDA will publish a Request for Proposals (RFP) to solicit proposals from outside research organizations to conduct research on determining the best way to maximize the public health benefit associated with collecting and reporting serious and non-serious adverse events occurring throughout a product's life cycle. Central to addressing this question are determining the number and type of safety concerns discovered by AE collection, the age of products at the time safety concerns are detected by AE collection, and the types of actions that are subsequently taken to protect patient safety. Contractor(s) should study adverse event collection both within and outside the U.S. Contract(s) will be awarded during FY 09 and the completion of study(ies) targeted for FY 11.

2. Epidemiology Best Practices and Guidance Document Development: During FY 08, the FDA, with input from academia, industry, and others from the general public, will hold a public workshop to identify epidemiology best practices. The workshop will examine current epidemiology practices both within and outside the U.S. By the end of FY 10, CDER and CBER jointly will develop and issue a draft guidance document that addresses epidemiology best practices and provides guidance on carrying out scientifically sound observational studies using quality data resources. A final guidance will be issued in FY 11.

3. Expanding Database Resources: A critical part of the transformation of the drug safety program is maximizing the usefulness of tools used for adverse event signal detection and risk assessment. To achieve this end, data other than passive spontaneous reports, including population-based epidemiological data and other types of observational data resources will be used and evaluated. Access to these types of data will expand the FDA's capability to carry out targeted postmarketing surveillance, look at class effects of drugs, and potentially carry out signal detection using data resources other than reports from AERs system. PDUFA funds will be used to obtain access to additional databases, to train existing staff, and to hire additional epidemiologists and programmers to be able to use these new resources.

4. Development and Validation of Risk Management and Risk Communication Tools: During FY 08, FDA will develop a plan to 1) identify, with input from academia, industry, and others from the general public, risk management tools and programs for the purpose of evaluation and 2) conduct assessments of the effectiveness of identified Risk Minimization Action Plans (RiskMAPS) and current risk management and risk communication tools. A public workshop will be held during FY 09 to obtain input from industry and other stakeholders regarding the prioritization of the plans and tools to be evaluated. Starting in FY 09, FDA will conduct annual systematic public discussion and review of the effectiveness of one to two risk management program(s) and one major risk management tool. Reports of these discussions will be posted on the FDA website.

C. Review of risk management plans

FDA may use user fees for the review of risk management plans and related activities (e.g., meeting with sponsors, collaborations between review divisions and the appropriate safety group in CDER or CBER, and reviews of periodic reports on the implementation of any risk management plan).

D. Other Activities

FDA will establish the following standards-based information systems to support how FDA obtains and analyzes post-market drug safety data and manages emerging drug safety information:

1. Enhanced adverse event reporting system and surveillance tools;

2. IT infrastructure to support access and analyses of externally-linked databases; and

3. Workflow tracking system.

IX. REVIEW OF PROPRIETARY NAMES TO REDUCE MEDICATION ERRORS

To enhance patient safety, FDA will utilize user fees to implement various measures to reduce medication errors related to look-alike and sound-alike proprietary names and such factors as unclear label abbreviations, acronyms, dose designations, and error prone label and packaging design.

A. Review Performance Goals—Drug/Biological Product Proprietary Names

1. Proprietary names submitted during IND phase (as early as end-of-phase 2)

a) Review 50% of proprietary name submissions filed during FY 09 within 180 days of receipt. Notify sponsor of tentative acceptance or non-acceptance.

b) Review 70% of proprietary name submissions filed during FY 10 within 180 days of receipt. Notify sponsor of tentative acceptance or non-acceptance.

c) Review 90% of proprietary name submissions filed during FYs 11 and 12 within 180 days of receipt. Notify sponsor of tentative acceptance or non-acceptance.

d) If proprietary name is found to be unacceptable, sponsor can request reconsideration by submitting a written rebuttal with supporting data or request a meeting within 60 days to discuss the initial decision (meeting package required).

e) If proprietary name is found to be unacceptable, the above review performance goals also would apply to the written request for reconsideration with supporting data or the submission of a new proprietary name.

f) Complete submission is required to begin the review clock.

2. Proprietary names submitted with NDA/BLA

a) Review 50% of NDA/BLA proprietary name submissions filed during FY 09 within 90 days of receipt. Notify sponsor of tentative acceptance/non-acceptance.

b) Review 70% of NDA/BLA proprietary name submissions filed during FY 10 within 90 days of receipt. Notify sponsor of tentative acceptance/non-acceptance.

c) Review 90% of NDA/BLA proprietary name submissions filed during FYs 11 and 12 within 90 days of receipt. Notify sponsor of tentative acceptance/non-acceptance.

d) A supplemental review will be done meeting the above review performance goals if the proprietary name has been submitted previously (IND phase after end of phase 2) and has received tentative acceptance.

e) If proprietary name is found to be unacceptable, sponsor can request reconsideration by submitting a written rebuttal with supporting data or request a meeting within 60 days to discuss the initial decision (meeting package required).

f) If proprietary name is found to be unacceptable, the above review performance goals apply to the written request for reconsideration with supporting data or the submission of a new proprietary name.

g) Complete submission is required to begin the review clock.

3. Guidance Document Development

a) By the end of FY 08, FDA will publish a final guidance on the contents of a complete submission package for a proposed proprietary drug/biological product name.

b) By the end of FY 09, FDA will prepare a MaPP (Manual of Policies and Procedures) to ensure that FDA internal processes (e.g., Division of Medication Errors and Technical Support, Division of Drug Marketing, Advertising, and Communications, Office of New Drugs, CDER and Advertising and Promotional Labeling Branch, CBER) are consistent with meeting the proprietary name review goals.

c) By the end of FY 10, after public consultation with academia, industry, and others from the general public, FDA will publish a draft guidance on best practices for naming, labeling and packaging drugs and biologics to reduce medication errors. Final guidance will be published by the end of FY 11.

d) By the end of FY 12, after public consultation with industry, academia and others from the general public, FDA will publish a draft guidance on proprietary name evaluation best practices. Publication of final guidance on proprietary name evaluation best practices will follow as soon as feasible.

B. Pilot Program

During PDUFA IV, FDA will develop and implement a pilot program to enable pharmaceutical firms participating in the pilot to evaluate proposed proprietary names and submit the data generated from those evaluations to the FDA for review.

1. FDA will hold a public technical meeting to discuss the elements necessary to create a concept paper describing the logistics of the pilot program, the contents of a proprietary name review submission, and the criteria to be used by FDA to review submissions under the pilot program. Subsequently, by the end of FY 08, FDA will publish the concept paper.

2. By the end of FY 09, FDA will begin enrollment into the pilot program.

3. By the end of FY 11, or subsequent to accruing two years of experience with pilot submissions, FDA will evaluate the pilot program.

C. Other Activities

1. FDA and industry are interested in exploring the possibility of ''reserving'' proprietary names for companies once the names have been tentatively accepted by the Agency. By the end of FY 08, FDA will initiate a public process to discuss issues around ''reserving'' proprietary names.

2. FDA will provide the full source code and supporting technical documentation for the Phonetic and Orthographic Computer Analysis (POCA) tool and make it available on disk for use by industry and others from the general public by end of FY 08.

X. FIRST CYCLE REVIEW PERFORMANCE PROPOSAL

A. Notification of Issues Identified during the Filing Review

1. Performance Goal: For original NDA/BLA applications and efficacy supplements, FDA will report substantive review issues identified during the initial filing review to the applicant by letter, telephone conference, facsimile, secure e-mail, or other expedient means.

2. The timeline for such communication will be within 14 calendar days after the 60-day filing date.

3. If no substantive review issues were identified during the filing review, FDA will so notify the applicant.

4. FDA's filing review represents a preliminary review of the application and is not indicative of deficiencies that may be identified later in the review cycle.

5. FDA will notify the applicant of substantive review issues prior to the goal date for 90% of applications.

B. Notification of Planned Review Timelines

1. Performance Goal: For original NDA/BLA applications and efficacy supplements, FDA will inform the applicant of the planned timeline for review of the application. The information conveyed will include a target date for communication of feedback from the review division to the applicant regarding proposed labeling and postmarketing study commitments (PMCs) the Agency will be requesting.

2. The planned review timeline will be included with the notification of issues identified during the filing review, within 14 calendar days after the 60-day filing date.

3. The planned review timelines will be consistent with the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products (GRMPs), taking into consideration the specific circumstances surrounding the individual application.

4. The planned review timeline will be based on the application as submitted.

5. FDA will inform the applicant of the planned review timeline for 90% of original BLA and NME NDA applications beginning in FY 09; 90% of efficacy supplements for new or expanded indications beginning in FY 10; 90% of all original NDAs/BLAs beginning in FY 11; and 90% of all efficacy supplements beginning in FY 12 (see table below).

(Percent)

	FY 08	FY 09	FY 10	FY 11	FY 12
Original BLAs and NME NDAs	—	90	90	90	90
Efficacy supplements for new/expanded indications	—	—	90	90	90
All original NDAs	—	—	—	90	90
All efficacy supplements	—	—	—	—	90

6. Should the applicant submit any unsolicited major amendment(s) to the application (e.g., a major new clinical safety/efficacy study report, major re-analyses of previously submitted study(ies)) and if the division chooses to review such amendment(s) during that review cycle, the planned review timeline will no longer be applicable (even if the unsolicited major amendment leads to an extension of the overall PDUFA review clock). No new planned review timeline need be provided in such cases; however, the overall PDUFA action goal date, including any extension, will still apply. The division will notify the applicant promptly of its decision regarding review of the unsolicited major amendment(s) and whether the planned review timeline is still applicable.

7. In the event FDA determines that significant deficiencies in the application preclude discussion of labeling or PMCs by the target date identified in the planned review timeline (e.g., failure to demonstrate efficacy, significant safety concern(s), need for a new study(ies) or extensive re-analyses of existing data before approval), FDA will communicate this determination to the applicant in accordance with GRMP and no later than the target date. In such cases the planned review timeline will be considered to have been met. Communication of FDA's determination may occur by letter, telephone conference, facsimile, secure e-mail, or other expedient means. Communication of the deficiencies identified will generally occur through issuance of a discipline review letter(s) in advance of the planned target date for initiation of postmarketing study commitments and labeling discussions.

8. Should the applicant submit a major amendment(s) (e.g., a major new clinical safety/efficacy study report, major re-analyses of previously submitted study(ies)) to provide information or data requested by FDA during the review (e.g., a solicited major amendment) and if the division chooses to review such amendment(s) during that review cycle, the planned review timeline initially communicated will generally no longer be applicable. If the solicited major amendment does not result in an extension of the overall PDUFA review clock, and depending upon the circumstances, the review division may choose to retain the previously communicated planned review timeline (e.g., the solicited major amendment is submitted early in the review cycle, review of the amendment is not expected to significantly alter the division's planned review timeline). If the solicited major amendment is submitted during the last 90 days of the review cycle and results in an extension of the PDUFA action date (review clock), the review division will establish a new review timeline for communication of feedback on proposed labeling and PMCs. The division will notify the applicant promptly of its decision regarding review of the major amendment(s) and whether the planned review timeline is still applicable. If the solicited major amendment results in an extension of the overall PDUFA review clock, the division will communicate a new planned review timeline to the applicant at the time of the clock extension.

C. Report on Review Timeline Performance

1. FDA will report its performance in meeting the goals for inclusion of a planned review timeline with the notification of issues identified during the filing review in the annual PDUFA performance report.

2. FDA will report its performance in meeting the planned review timeline for communication of labeling comments and PMC requests in the annual PDUFA performance report. The report will include the percentage of applications for which the planned target dates for communication of labeling comments and PMC requests were met. The report will also note how often the planned review timeline was met based on communication of labeling comments and PMC requests by the target date and how often such communication did not occur due to FDA's determination that significant deficiencies in the application precluded communication of labeling comments and PMC requests at the time initially projected. Communication of labeling comments and PMC requests, or communication of FDA's determination that significant deficiencies preclude initiation of such discussions, within 7 calendar days of the target date stated in the planned review timeline will be considered to have met the target date. FDA will also report the number of times that the review timelines were inapplicable due to the Agency's decision to review an unsolicited major amendment or a solicited major amendment that did not result in an extension of the review clock (unless the review division chose to retain the previously communicated planned review timeline.)

3. FDA will engage an independent outside consultant to conduct an analysis of the Agency's success in adhering to the planned review timelines. The contractor will assess the factors, based on input from both the FDA and the applicants, that contributed to the ability of the Agency to adhere to the planned review timelines and those factors attributable to either the FDA or the applicant that contributed to failure to adhere to the planned review timeline. A final report will be provided to FDA at least 6 months before the end of FY 11. FDA will make available a releasable version of the final report within 2 months of receipt from the independent outside consultant.

D. Standard Operating Procedures and Training

FDA will develop harmonized (CBER/CDER) standard operating procedures (SOPs) regarding the notification of planned review timelines. These SOPs will be finalized and implemented by the end of FY 08. Training will be provided to all CBER and CDER review staff on the harmonized (CBER/CDER) standard operating procedures. Training will continue for all new review staff and refresher training will be provided to all review staff as necessary through FY 12.

XI. EXPEDITING DRUG DEVELOPMENT

A. Guidance Development: FDA will develop and publish for comment draft guidances on the following topics by the end of the indicated Fiscal Year of PDUFA-IV. FDA will complete the final guidances within one year of the close of the public comment period.

1. Clinical Hepatotoxicity—FY 2008
2. Non-inferiority Trials—FY 2008
3. Adaptive Trial Designs—FY 2008
4. End of Phase 2(a) Meetings—FY 2008
5. Multiple Endpoints in Clinical Trials—FY 2009
6. Enriched Trial Designs—FY 2010
7. Imaging Standards for Use as an End Point in Clinical Trials—FY 2011

B. Ongoing Scientific Collaboration: FDA will participate in workshops with representatives from the scientific community (including industry, academia and other interested stakeholders) to further the science toward development of guidance documents in the following areas:

1. Predictive Toxicology
2. Biomarker Qualification
3. Missing Data

C. FDA will participate in workshops and other public meetings to explore new approaches to a structured model for benefit/risk assessment. The results of these interactions will be used to assess whether pilot(s) of such new approaches can be conducted during PDUFA–IV. These efforts may lead to the development of guidance documents.

XII. POSTMARKETING STUDY COMMITMENTS

FDA will develop harmonized (CBER/CDER) standard operating procedures that articulate the Agency's policy and procedures (e.g., timing, content, rationale and vetting process) for requesting that applicants agree in writing to voluntary postmarketing study commitments. The SOPs will be finalized prior to the end of FY 08. In developing these SOPs, the Agency will take into consideration the findings of the contractor study of current Agency procedures to be completed during FY 07. FDA will make available a releasable version of the final report within 2 months of receipt from the contractor. Training will be provided to all CBER and CDER review staff on the harmonized (CBER/CDER) standard operating procedures. Training will continue for all new review staff and refresher training will be provided to all review staff as necessary through FY 12.

XIII. IMPROVING FDA PERFORMANCE MANAGEMENT

A. The studies conducted under this initiative are intended to foster:

1. Development of programs to improve access to internal and external expertise
2. Reviewer development programs, particularly as they relate to drug review processes
3. Advancing science and use of information management tools
4. Improving both inter- and intra-Center consistency, efficiency, and effectiveness
5. Improved reporting of management objectives
6. Increased accountability for use of user fee revenues
7. Focused investments on improvements in the process of drug review
8. Improved communication between the FDA and industry

B. Studies will include:

1. Assessment of the impact of the electronic submission and review environment on the efficiency and effectiveness of the overall process for the review of human drugs.

2. Assessment of the progress toward full implementation of Good Review Management Principles, focusing on both FDA reviewer practices and industry sponsor practices affecting successful implementation.

3. Assessment by an independent accounting firm of the review activity adjustment methodology (as described in section 736(c)(2) that is applied in FY 09 with recommendations for changes, if warranted

XIV. INFORMATION TECHNOLOGY GOALS

A. Objectives

1. FDA is committed to achieve the long-term goal of an automated standards-based information technology (IT) environment for the exchange, review, and management of information supporting the process for the review of human drug applications throughout the product life cycle. Towards this goal, FDA will work toward the accomplishment of the following objectives by the end of FY 12:

a) Develop and periodically update an IT plan, as defined in Sections B) and C) below, covering a rolling five-year planning horizon.

b) Develop, implement, and maintain new information systems consistently across all organizational divisions participating in the process for the review of human drug applications, and in compliance with the IT plan, the FDA's program-wide governance process, the FDA's target enterprise architecture, and with HHS enterprise architecture standards. The consistency of development, implementation, and maintenance of new information systems will be determined by the FDA based on considerations of program efficiency and effectiveness. Emphasis will be placed on the consistency of interactions with regulated parties and other external stakeholders.

c) Update technical specifications and IT-related guidance documents as necessary to reflect consistent program-wide implementation of new information systems supporting electronic information exchange between FDA and regulated parties and other external stakeholders.

d) Extend the capability of the secure electronic single point of entry to include two-way transmission of regulatory correspondence.

e) Establish an automated standards-based regulatory submission and review environment for INDs, NDAs, and BLAs, and their supplements, that enables the following functions over the life cycle of the product:

(1) Electronic IND, NDA, and BLA submissions received by FDA can be archived to enable retrieval through standardized automated links;

(2) Electronic IND, NDA, and BLA submissions can include cross-references to previously submitted electronic materials through standardized automated links; and

(3) Archived electronic IND, NDA, and BLA submissions can be retrieved through standardized automated links.

f) Establish a system for electronic exchange and management of human drug labeling information in a modular manner (e.g., at the label section level) that is based on FDA standards and that enables revision tracking.

g) Establish standards-based information systems to support how FDA obtains and analyzes post-market drug safety data and manages emerging drug safety information, as described in Section VIII addressing the enhancement and modernization of the FDA drug safety system.

B. Communications and Technical Interactions

1. FDA will develop and periodically update a five-year IT plan for improving the automation of business processes and acquiring and maintaining information systems to achieve the objectives defined above in PDUFA IT Goal A. The plan will include measurable or observable milestones toward achievement of those objectives.

2. The IT plan will be reviewed and approved through the appropriate FDA governance process to ensure it conforms to the Agency's overall long-term automation strategy.

3. The IT plan will be drafted, published on the FDA web site, and updated as follows:

a) FDA will publish a draft of the IT plan by December 31, 2007. At that time, FDA will solicit and consider comments from the public on the draft IT plan. The public comment period will be at least 45 calendar days. FDA will complete revisions to the IT plan and publish the final version no later than May 30, 2008.

b) FDA will conduct an annual assessment of progress against the IT plan and publish on the FDA web site a summary of the assessment within 2 months after the close of each fiscal year.

c) FDA will publish updates to the IT plan as FDA deems necessary to achieve the objectives defined in PDUFA IT Goal A. FDA will publish on the FDA web site draft revisions to the IT plan; solicit comments from the public on those draft revisions; and consider the public comments before completing and publishing updates to the IT plan.

4. The FDA and industry stakeholders will meet on a quarterly basis to discuss ongoing implementation of the IT plan, status of IT metrics as available, and potential impacts that future activities may have on stakeholders. These meetings will also be used to discuss potential FDA revisions to the IT plan based on operational experience.

C. Standards and IT Plan

The IT plan referenced in PDUFA IT Goal B will provide a vision for FDA standards and technical infrastructure supporting the process for the review of human drug applications and will address the following:

1. A description of the scope and approach for an evaluation and design of the target enterprise architecture necessary to achieve the objectives defined in PDUFA IT Goal A.

2. The business processes targeted for automation to achieve business-driven objectives.

3. Which electronic data standards, including the associated Standards Development Organization, are being considered for adoption or development. (Note: The FDA's process for adopting or developing standards includes the consideration of existing open consensus standards prior to the development of new standards. FDA participates in international Standards Development Organizations and supports global harmonization of data standards through open structured processes.)

4. Implementation of information systems that are based on the electronic data standards.

5. Training for system users, stakeholder adoption, and communications for transitioning to new or reengineered information systems supporting the process for the review of human drug applications.

6. A description of FDA's processes for

a) evaluating business processes for electronic information exchange between FDA and regulated parties or external stakeholders;

b) evaluating, adopting or developing electronic data standards for information exchange between FDA and regulated parties or external stakeholders; and

c) developing, piloting, and deploying information systems that use those standards in supporting the process for the review of human drug applications.

D. Metrics and Measures

FDA will measure progress toward achievement of the objectives defined in PDUFA IT Goal A. Measures will include:

1. The number and percentage of IND, NDA, and BLA submissions received in valid electronic format in compliance with FDA standards, categorized by types of submissions. Increasing the number and percentage of IND, NDA, and BLA submissions received in valid electronic format is a goal that is supported by the FDA and industry stakeholders. Achievement of this goal requires the cooperation of regulated industry. To support the assessment of this goal, the following information will be tracked and reported at least annually:

a) Total number of submissions categorized by type of submission;

b) Total number of submissions in valid electronic format in compliance with FDA standards

c) Total number of submissions received through the secure electronic single point of entry versus other methods; and

d) Total number of submissions received substantially on paper.

2. Total number of standards-based electronic submissions that fail to comply with FDA electronic submission standards, along with a distribution of these submission failures across categories of failure or problem type.

3. Annual spending on maintenance of legacy IT systems and IT systems that are common across the organizational divisions participating in the process for the review of human drug applications.

4. Other measures and milestones to be identified in the IT plan addressed under Sections B and C above.

XV. DEFINITIONS AND EXPLANATION OF TERMS

A. The term ''review and act on'' is understood to mean the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

B. A major amendment to an original application, efficacy supplement, or resubmission of any of these applications, submitted within three months of a goal date, may extend the goal date by three months. A major amendment to a manufacturing supplement submitted within two months of the goal date extends the goal date by two months. Only one extension can be given per review cycle.

C. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

D. Class 1 resubmitted applications are applications resubmitted after a complete response letter (or a not approvable or approvable letter) that include the following items only (or combinations of these items):

1. Final printed labeling

2. Draft labeling

3. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission)

4. Stability updates to support provisional or final dating periods

5. Commitments to perform Phase 4 studies, including proposals for such studies

6. Assay validation data

7. Final release testing on the last 1–2 lots used to support approval

8. A minor reanalysis of data previously submitted to the application (determined

* * *

9. Other minor clarifying information (determined by the Agency as fitting the Class 1 category)

10. Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.

E. Class 2 resubmissions are resubmissions that include any other items, including any items that would require presentation to an advisory committee.

F. A Type A meeting is a meeting which is necessary for an otherwise stalled drug development program to proceed (a ''critical path'' meeting) or to address an important safety issue.

G. A Type B Meeting is a 1) pre-IND, 2) end of Phase 1 (for Subpart E or Subpart H or similar products) or end of Phase 2/pre-Phase 3, or 3) a pre-NDA/BLA meeting. Each requestor should usually only request 1 each of these Type B meetings for each potential application (NDA/BLA) (or combination of closely related products, i.e., same active ingredient but different dosage forms being developed concurrently).

H. A Type C meeting is any other type of meeting.

I. The performance Goals and procedures also apply to original applications and supplements for human drugs initially marketed on an over-the-counter (OTC) basis through an NDA or switched from prescription to OTC status through an NDA or supplement.

J. IT Definitions (see section XI)

1. ''Automation of business processes'' refers to the development and deployment of information systems that support program activities (i.e., business processes) conducted under the process for the review of human drug applications. The purpose of business process automation is to support decision making by FDA program managers and reviewers. The scope of business process automation is determined by program managers toward the objective of more efficient and effective program operations.

2. ''Program'' refers to the organizational resources, procedures, and activities assigned to conduct ''the process for the review of human drug applications,'' as defined in the Prescription Drug User Fee Act.

3. ''Standards-based'' means compliant with published specifications that address terminology or information exchange between the FDA and regulated parties or external stakeholders, as adopted by the FDA or other agencies of the federal government, and often based on the publications of national or international Standards Development Organizations.

4. ''FDA Standards'' means technical specifications that have been adopted and published by the FDA through the appropriate governance process. FDA standards may apply to terminology, information exchange, engineering or technology specifications, or other technical matters related to information systems. FDA standards often are based on the publications of other federal agencies, or the publications of national or international Standards Development Organizations.

5. ''Product life cycle'' means the sequential stages of human drug development, regulatory review and approval, post-market surveillance and risk management, and where applicable, withdrawal of an approved drug from the market. In the context of the process for the review of human drug applications, the product life cycle begins with the earliest regulatory submissions in the Investigational New Drug (IND) phase, continues through the New Drug Application (NDA) or Biological Licensing Application (BLA) review phase, and includes post-market surveillance and risk management activities as covered under the process for the review of human drug applications.

6. ''The FDA's program-wide IT governance process'' includes centralized oversight of all data and technology standards adoption, technology acquisition, and funding allocation.

7. ''The FDA's target enterprise architecture'' includes data and technology standards for the electronic exchange and management of information supporting the process for the review of human drug applications.

SECTION B: PERFORMANCE GOALS AND PROCEDURES FOR ADVISORY REVIEW OF DIRECT-TO-CONSUMER TELEVISION ADVERTISING FISCAL YEARS 2008 THROUGH 2012

The performance goals and procedures of the FDA Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), as agreed to under the direct-to-consumer television advertising user fee program in Section 736A of the Federal Food, Drug, and Cosmetic Act are summarized below.

I. FINDINGS

A. FDA's advisory review of proposed prescription drug television advertisements helps to ensure that these advertisements communicate information to consumers that is accurate, balanced, and adequately substantiated, thereby improving the quality of these advertisements.

B. It is important to industry and FDA to provide predictability in the timeframe for reviewing and providing written comments on direct-to-consumer television advertisements submitted to FDA for advisory review before initial dissemination.

C. FDA needs additional resources to ensure that it has adequate staff to provide advisory reviews of direct-to-consumer television advertisements in a timely manner.

D. A program that requires payment of user fees by those who choose to voluntarily submit direct-to-consumer television advertisements for advisory review by FDA is established to provide needed resources to FDA and improve the timeliness of FDA advisory reviews while maintaining the quality of the reviews.

E. Each submission for advisory review will be assessed a fee, but the sponsor may resubmit that advertisement one time after receiving comments without further fee assessment.

F. Under this program, it is important to ensure that FDA has the resources needed to hire and retain adequate staff to meet review performance goals.

G. Because reviews from this program are dependant on submissions which are unpredictable, the statute establishes a reserve fund to maintain a staff that can meet the review performance goals in case user fees for any year of the program are not adequate. In addition, user fees for all submissions during a fiscal year are to be paid at the start of each fiscal year or late fees will be assessed.

II. REVIEW PERFORMANCE GOALS

A. Goals for First 150 Advisory Review Submissions.

Fiscal Year 2008:

1. Review and provide advisory comments for 75 original submissions within 45 days (50% of 150).

2. Review and provide advisory comments for 37 resubmissions of original submissions within 30 days (50% of 75 resubmissions).

Fiscal Year 2009:

1. Review and provide advisory comments for 90 original submissions (60% of 150) within 45 days.

2. Review and provide advisory comments for 45 resubmissions (60% of 75) within 30 days.

Fiscal Year 2010:

1. Review and provide advisory comments for 105 original submissions (70% of 150) within 45 days.

2. Review and provide advisory comments for 52 resubmissions (70% of 75) within 30 days.

Fiscal Year 2011:

1. Review and provide advisory comments for 120 original submissions (80% of 150) within 45 days.

2. Review and provide advisory comments for 60 resubmissions (80% of 75) within 30 days.

Fiscal Year 2012:

1. Review and provide advisory comments for 135 original submissions (90% of 150) within 45 days.

2. Review and provide advisory comments for 68 resubmissions (90% of 75) within 30 days.

NOTE: For any goal year, if the number of submissions or resubmissions received is not greater than the number for which the Agency has committed to provide advisory comments on within the goal timeframe, then the goal will be to provide comments on 90% of the number received within the goal timeframe. For example, if FDA receives only 30 resubmissions in fiscal year 2008, then the goal would be to review 27 resubmissions within 30 days.

B. Goals after 150 Submissions

If in any fiscal year after FY 2008, participants in the program indicate (in response to the Federal Register notice) the intent to submit more direct-to-consumer broadcast advertisement submissions for advisory review than were subject to the goals in the prior year, the following performance goals will apply (see Appendix B–1 for specific examples):

1. In the first year of the increase, FDA will review and provide advisory comments for:

a) 50% of the additional paid original submissions over the cohort of original submissions from the previous fiscal year, up to a maximum of 50 additional submissions, within 45 days.

b) 50% of the additional resubmissions over the cohort of resubmissions from the previous fiscal year, up to a maximum of 24 additional resubmissions, within 30 days.

2. In each subsequent year, the performance goals will increase in the same manner as in section A. for each additional cohort of up to 50 additional submissions over the cohort of the prior year (i.e., in the second year after the increase, the goal will be to review 60% of the additional cohort from the prior year (up to 50 submissions) and 50% of any further additions (up to an additional 50 submissions)).

3. For purposes of this adjustment, it is assumed that the number of submissions subject to review metrics cannot decrease from one year to the next even if actual submissions decrease.

4. For purposes of this adjustment, it is assumed that 150 submissions are subject to performance goals in fiscal year 2008.

5. The goals described in this subsection will be calculated based solely on the number of submissions identified in response to the Federal Register notice for that fiscal year.

III. DEFINITIONS AND EXPLANATION OF TERMS

1. The term ''amendment'' shall mean additional documents submitted to FDA to complete an original submission or resubmission. For example, references that have been cited in the original submission but were omitted from the original submission package could be submitted as an amendment.

2. The term ''original submission'' shall mean a proposed television advertisement submission for which a sponsor paid for an advisory review. The proposed television advertisement may not be more than two minutes long.

3. The term ''resubmission'' shall mean a subsequent submission of a revised version of the advertisement contained in an original submission. Any revisions made to the proposed television advertisement must be based on FDA comments on the original submission. The resubmission may not introduce significant new concepts or creative themes into the television advertisement, or

FDA will designate it as an original submission. Revisions that require a consult to another division will be considered to introduce ''significant new concepts or creative themes.''

APPENDIX B–1

EXAMPLE 1: ORIGINAL SUBMISSIONS

If participants indicate the intent to submit 150 submissions in fiscal year 2008; 200 submissions in fiscal year 2009; 224 submissions in fiscal year 2010; 200 submissions in fiscal year 2011; and 250 submissions in fiscal year 2012, the review metrics will be as follows:

	FY 08: 150 submissions	FY 09: 200 submissions	FY 10: 224 submissions	FY 11: 200 submissions	FY 12: 250 submissions
Cohort 1 (150 submissions)	75 (50% of 150)	90 (60% of 150)	105 (70% of 150)	120 (80% of 150)	135 (90% of 150)
Cohort 2 (50 submissions)		25 (50% of 50)	30 (60% of 50)	35 (70% of 50)	40 (80% of 50)
Cohort 3 (24 submissions)			12 (50% of 24)	0 (60% of 0)	17 (70% of 24)
Cohort 4 (0 submissions)				0 (50% of 0)	0 (70% of 0)
Cohort 5 (26 submissions)					13 (50% of 26)
Total Target for 45 Day Review Metric	75	115	147	155	205

EXAMPLE 2: ORIGINAL SUBMISSIONS

If participants indicate the intent to submit 150 submissions in fiscal year 2008; 200 submissions in fiscal year 2009; 250 submissions in fiscal year 2010; 300 submissions in fiscal year 2011; and 350 submissions in fiscal year 2012, the review metrics will be as follows:

	FY 08: 150 submissions	FY 09: 200 submissions	FY 10: 250 submissions	FY 11: 300 submissions	FY 12: 350 submissions
Cohort 1 (150 submissions)	75 (50% of 150)	90 (60% of 150)	105 (70% of 150)	120 (80% of 150)	135 (90% of 150)
Cohort 2 (50 submissions)		25 (50% of 50)	30 (60% of 50)	35 (70% of 50)	40 (80% of 50)
Cohort 3 (50 submissions)			25 (50% of 50)	30 (60% of 50)	35 (70% of 50)
Cohort 4 (50 submissions)				25 (50% of 50)	30 (60% of 50)
Cohort 5 (50 submissions)					25 (50% of 50)
Total Target for 45 Day Review Metric	75	115	160	210	265

EXAMPLE 3: RESUBMISSIONS

If participants submit 75 resubmissions in fiscal year 2008; 99 resubmissions in fiscal year 2009; 123 resubmissions in fiscal year 2010; 147 resubmissions in fiscal year 2011; and 171 resubmissions in fiscal year 2012, the review metrics will be as follows:

	FY 08: 75 resubmissions	FY 09: 99 resubmissions	FY 10: 123 resubmissions	FY 11: 147 resubmissions	FY 12: 171 resubmissions
Cohort 1 (75 submissions)	37 (50% of 75)	45 (60% of 75)	52 (70% of 75)	60 (80% of 75)	68 (90% of 75)
Cohort 2 (24 submissions)		12 (50% of 24)	14 (60% of 24)	17 (70% of 24)	19 (80% of 24)
Cohort 3 (24 submissions)			12 (50% of 24)	14 (60% of 24)	17 (70% of 24)
Cohort 4 (24 submissions)				12 (50% of 24)	14 (60% of 24)
Cohort 5 (24 submissions)					12 (50% of 24)
Total Target for 30 Day Review Metric	37	57	78	103	130

IRAQ STUDY GROUP

Mr. SALAZAR. Mr. President, last night, we passed the Department of Defense Authorization bill. I want to comment briefly on the debate we had during consideration of that legislation related to the war in Iraq. I am frustrated that we did not reach a bipartisan consensus on a new way forward that could begin to bring an end to this conflict.

When I introduced the Iraq Study Group Recommendations Implementation Act last spring with Senator ALEXANDER and a bipartisan group of our colleagues, I was hopeful we could work constructively with the President toward the goal of having our troops redeployed by the spring of 2008. I was hopeful that we would send a strong signal—with a bipartisan group that eventually grew to 17 Senators—that we should get out of the combat business in Iraq as quickly as possible.

The Iraq Study Group Report was issued 10 months ago. Its core recommendation was that we transition our military mission from combat to training, supporting, and equipping Iraqi security forces. The report said that we should condition our support of the Iraqi Government on its performance in meeting important milestones. The report contemplated that we could be out of the combat business by March 31, 2008.

The report was anticipated with great fanfare. But when it came out, the Bush administration failed to embrace it. The Iraqi Government has failed to meet most of the benchmarks described in the report. General Petraeus has testified, essentially, that we should maintain our combat mission for the foreseeable future. And that March 31 date is only 6 months away.

I still believe in the report. It is still relevant, and it is still important. It sets forth a comprehensive military, political, and economic strategy for bringing a responsible end to the war in Iraq.

But I believe we must build upon the report and take decisive action now to redefine our mission in Iraq and set a clear course for the redeployment of our troops.

Ten months after the Iraq Study Group issued its report, we have failed to begin the transition of our mission that was central to their recommendations. That transition in mission is the key to encouraging the Iraqi Government to take responsibility for the future of their country. The Government Accountability Office has concluded that the Iraqi Government has failed to take that responsibility by meeting the reasonable benchmarks set forth by the Iraq Study Group.

I continue to believe that we must follow the core principles laid out in the Iraq Study Group Report. I continue to believe we need a bipartisan solution to bring this conflict to a responsible end. And I thank each of the cosponsors of our amendment, Republicans and Democrats, for their willingness to join in this important effort. They include Senators ALEXANDER, BENNETT, COLEMAN, COLLINS, DOMENICI, GREGG, SPECTER, and SUNUNU from the Republican side and Democratic Senators PRYOR, CASEY, CARPER, CONRAD, LANDRIEU, LINCOLN, MCCASKILL, and BILL NELSON.

I believe now is the time to build upon the principles set forth by the Iraq Study Group. We must begin a transition of mission from combat to training and support. We must demand more from the Iraqi Government and send a strong and unequivocal message that our commitment is not open-ended. I believe these actions are consistent with the recommendations of the Iraq Study Group, and I remain hopeful that our legislation can be the basis for a constructive, bipartisan solution to the war in Iraq.

HONORING OUR ARMED FORCES

SECOND CLASS CHARLES LUKE MILAM

Mr. SALAZAR. Mr. President, I wish to reflect on the life and service of Navy Hospital Corpsman Second Class Charles Luke Milam. Luke was killed last Wednesday in a rocket attack near the town of Musa Qula, Afghanistan. He was 26 years old.

Luke Milam was a giant of his generation, a man who served his country and those around him with dignity, courage, and honor. I cannot begin to paint the picture of someone so deeply respected by those with whom he served, so committed to helping others.

Luke Milam grew up in Littleton, CO, the youngest of four siblings. He was smart, friendly, and athletic. He loved the mountains of Colorado and spent his time biking, backpacking, hiking, and canoeing.