made necessary by this year's failure to fund the preservation program. While the House bill differs slightly from the Senate bill in its time extension, I am quite hopeful that the Senate will concur with this small change.

Mr. Speaker, the Department of Housing and Urban Development supports this legislation and has sent a letter indicating its support. The bill is also endorsed by the AARP. The legislation represents the hard work of the Committee on Banking and Financial Services which authorizes the housing programs. If we fail to take action today, many of the important provisions will be delayed for many, many months to come at the least. Therefore, I urge the adoption of this legislation.

Again, let me thank the gentleman from New York [Mr. LAZIO] for the hard work that he and his staff and the staff on the Democratic side have put into bringing this bill about today.

Mr. Speaker, I reserve the balance of my time.

Mr. LAZIO of New York. Mr. Speaker, I yield myself such time as I may consume. I would like to thank again the gentleman from Massachusetts [Mr. KENNEDY] for his hard work on this. This will be the third time actually that these provisions protecting seniors will have passed on the House floor. We have some additional provisions I think that will be helpful, in particular the flood insurance provisions which have been mentioned by both myself and by the gentleman from Massachusetts [Mr. KENNEDY].

Mr. Speaker, let me take this opportunity if I can to bid farewell to somebody who has served Congress very well, very admirably and will be missed I know on both sides of the aisle, and that is Kelsay Meek, who has been the staff director I know of the committee and has served with distinction. I know we have already had plenty of opportunity to acknowledge the contributions that the gentleman from Texas [Mr. GONZALEZ] has made to this body and to America. I want to reiterate again my respect for him, and again, my hat off to Kelsay Meek and wish him good luck in his future endeavors.

Mr. Speaker, I yield back the balance of my time.

Mr. KENNEDY of Massachusetts. Mr. Speaker, I yield myself such time as I may consume. I want to just let the chairman of the Subcommittee on Housing and Economic Opportunities know how much I appreciate his mentioning not only Kelsay Meek. Obviously this has come as a result of the retirement of one of the great Members and great advocates of housing policies in this country, HENRY GONZALEZ, who is going back to Texas and leaves a tremendous staff that has been dedicated to him.

Kelsay is the leader of that staff, and someone whom I have come to know and deeply appreciate in terms of his knowledge of housing issues and his deep commitment to protecting the very, very poor people of this country, but he also has many other members of his staff that are also moving on. We wish all of those the best, and are delighted that many of the members of the staff are going to be staying to do battle with others on the other side of the aisle at times in the future.

I do want to also acknowledge, while we have just a moment on the House floor, the fact that I know the gentleman from New York [Mr. LAZIO] and I will miss the gentleman from New York [Mr. FLAKE], a dear friend who is leaving the committee, another fine member of the Committee on Banking and Financial Services who did tremendous work on housing issues over the course of his career. I know he is going back to the city of New York. It is the first time I have had a chance to just acknowledge the loss of a deep personal friend here in the House who will be going back but serving a higher calling than perhaps even we in the House of Representatives.

Mr. Speaker, I thank the chairman of the committee for his actions, and I yield back the balance of my time.

The SPEAKER pro tempore [Mr. SNOWBARGER]. The question is on the motion offered by the gentleman from New York [Mr. LAZIO] that the House suspend the rules and agree to the resolution, House Resolution 329.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the resolution was agreed to.

A motion to reconsider was laid on the table.

GENERAL LEAVE

Mr. LAZIO of New York. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on S. 562.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New York?

There was no objection.

CORRECTING ENROLLMENT OF S. 830, FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

Mr. BURR of North Carolina. Mr. Speaker, I move to suspend the rules and agree to the concurrent resolution (H. Con. Res. 196) to correct the enrollment of the bill S. 830.

The Clerk read as follows:

H. CON. RES. 196

Resolved by the House of Representatives (the Senate concurring), That, in the enrollment of the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, the Secretary of the Senate shall make the following corrections:

(1) In section 119(b) of the bill:

(A) Strike paragraph (2) (relating to conforming amendments).

(B) Strike ''(b) SECTION 505(j).—'' and all that follows through '''(3)(A) The Secretary shall'' and insert the following:

''(b) SECTION 505(j).—Section 505(j) (21 U.S.C. 355(j)) is amended by adding at the end the following paragraph:

'''(9)(A) The Secretary shall''.

(2) In section 123 of the bill, strike subsection (g) and insert the following:

''(g) APPLICATION OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

''(1) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by subsection (d), is further amended by adding at the end the following:

'''(j) The Federal Food, Drug, and Cosmetic Act applies to a biological product subject to regulation under this section, except that—

'''(1) a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act; and

'''(2) the amendments made to section 505 of such Act by title I of Public Law 98–417 shall not apply to a biological product for which a license has been approved under subsection (a).'''.

''(2) RULE OF CONSTRUCTION.—Nothing in this Act or the amendments made by this Act shall affect the question of the applicability of any provision of section 505 of the Federal Food, Drug, and Cosmetic Act to a biological product for which an application has been approved under section 505 of such Act.''.

(3) In section 125(d)(2) of the bill, in the matter preceding subparagraph (A), insert after ''antibiotic drug'' the second place such term appears the following: ''(including any salt or ester of the antibiotic drug)''.

(4) In section 127(a) of the bill: In section 503A of the Federal Food, Drug, and Cosmetic Act (as proposed to be inserted by such section 127(a)), in the second sentence of subsection (d)(2), strike ''or other criteria'' and insert ''and other criteria''.

(5) In section 412(c) of the bill:

(A) In subparagraph (1) of section 502(e) of the Federal Food, Drug, and Cosmetic Act (as proposed to be amended by such section 412(c)), in subclause (iii) of clause (A), insert before the period the following: ''or to prescription drugs''.

(B) Strike ''(c) MISBRANDING.—Subparagraph (1) of section 502(e)'' and insert the following:

''(c) MISBRANDING.—

''(1) IN GENERAL.—Subparagraph (1) of section 502(e)''.

(C) Add at the end the following:

''(2) RULE OF CONSTRUCTION.—Nothing in this Act or the amendments made by this Act shall affect the question of the authority of the Secretary of Health and Human Services regarding inactive ingredient labeling for prescription drugs under sections of the Federal Food, Drug, and Cosmetic Act other than section 502(e)(1)(A)(iii).''.

(6) Strike section 501 of the bill and insert the following:

''SEC. 501. EFFECTIVE DATE.

''(a) IN GENERAL.—Except as otherwise provided in this Act, this Act and the amendments made by this Act shall take effect 90 days after the date of enactment of this Act.

''(b) IMMEDIATE EFFECT.—Notwithstanding subsection (a), the provisions of and the amendments made by sections 111, 121, 125, and 307 of this Act, and the provisions of section 510(m) of the Federal Food, Drug, and Cosmetic Act (as added by section 206(a)(2)), shall take effect on the date of enactment of this Act.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from North Carolina [Mr. BURR] and the gentleman from Ohio [Mr. BROWN] each will control 20 minutes.

The Chair recognizes the gentleman from North Carolina [Mr. BURR].

GENERAL LEAVE

Mr. BURR of North Carolina. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous material on this legislation.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from North Carolina?

There was no objection.

Mr. BURR of North Carolina. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today to ask support for a concurrent resolution to correct the enrollment of S. 830, the Food and Drug Administration Modernization Act of 1997. This concurrent resolution makes 6 small changes in the FDA reform act to correct technical drafting problems that have been identified since the bill was passed in the House and voice voted on Sunday. This concurrent resolution corrects section references, clarifies the definition of terms used in the bill, makes grammatical changes and corrects the effective date of the act. These corrections have the full support of the Republican and Democrat sponsors of this legislation in both the House and the Senate.

In addition, I have a letter from Health and Human Services Secretary Donna Shalala regarding the user fees authorized by this act. These fees will be dedicated toward expediting the drug development process and the review of human drug applications. The specific performance goals that FDA has agreed to which are referenced in section 101(4) of this act are specified in the letter entitled PDUFA Reauthorization Performance Goals and Procedures from Secretary Shalala.

Mr. Speaker, I hope that these corrections will be adopted by the entire House.

Mr. Speaker, the text of the letter is as follows:

THE SECRETARY OF
HEALTH AND HUMAN SERVICES,
Washington, DC, November 13, 1997.

Hon. THOMAS J. BLILEY, Jr.,
Committee on Commerce, House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: As you are aware, the Prescription Drug User Fee Act of 1992 (PDUFA) expired at the end of Fiscal Year 1997. Under PDUFA, the additional revenues generated from fees paid by the pharmaceutical and biological prescription drug industries have been used to expedite the prescription drug review and approval process, in accordance with performance goals that were developed by the Food and Drug Administration (FDA) in consultation with the industries. To date, FDA has met or exceeded the review performance goals agreed to in 1992, and is reviewing over 90 percent of priority drug applications in 6 months and standard drug applications in 12 months.

FDA has worked with representatives of the pharmaceutical and biological prescription drug industries, and the staff of your Committee, to develop a reauthorization proposal for PDUFA that would build upon and enhance the success of the original program. Title I, Subtitle A of the Food and Drug Administration Modernization Act of 1997, S. 830, as passed by the House and Senate on November 9, 1997, reflects the fee mechanisms developed in these discussions. The performance goals referenced in Section 101(4) are specified in the enclosure to this letter, entitled ''PDUFA Reauthorization Performance Goals and Procedures.'' I believe they represent a realistic projection of what FDA can accomplish with industry cooperation and the additional resources identified in the bill.

This letter and the enclosed goals document pertain only to Title I, Subtitle A (Fees Relating to Drugs) of S. 830, the Food and Drug Administration Modernization Act of 1997).

OMB has advised that there is no objection to the presentation of these views from the standpoint of the Administration's program.

We appreciate the support of you and your staffs, the assistance of other Members of the Committee, and that of the Appropriations Committees, in the reauthorization of this vital program.

Sincerely,

DONNA E. SHALALA.

Enclosure.

PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES

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 ''Food and Drug Administration Modernization Act of 1997,'' are summarized as follows;

I. FIVE-YEAR REVIEW PERFORMANCE GOALS

Fiscal year 1998

1. Review and act on 90 percent of standard original New Drug Application (NDAs) and Product License Applications (PLAs)/Biologic License Applications (BLAs) filed during fiscal year 1998 within 12 months of receipt.

2. Review and act on 90 percent of priority original NDA and PLA/BLA submissions filed during fiscal year 1998 within 6 months of receipt.

3. Review and act on 90 percent of standard efficacy supplements filed during fiscal year 1998 within 12 months of receipt.

4. Review and act on 90 percent of priority efficacy supplements filed during fiscal year 1998 within 6 months of receipt.

5. Review and act on 90 percent of manufacturing supplements filed during fiscal year 1998 within 6 months of receipt.

6. Review and act on 90 percent of all resubmitted original applications filed during fiscal year 1998 within 6 months of receipt, and review and act on 30 percent of Class 1 resubmitted original applications within 2 months of receipt.

Fiscal year 1999

1. Review and act on 90 percent of standard original NDA and PLA/BLA submissions filed during fiscal year 1999 within 12 months of receipt and review and act on 30 percent within 10 months of receipt.

2. Review and act on 90 percent of priority original NDA and PLA/BLA submissions filed during fiscal year 1999 within 6 months of receipt.

3. Review and act on 90 percent of standard efficacy supplements filed during fiscal year 1999 within 12 months of receipt and review and act on 30 percent within 10 months of receipt.

4. Review and act on 90 percent of priority efficacy supplements filed during fiscal year 1999 within 6 months of receipt.

5. Review and act on 90 percent of manufacturing supplements filed during fiscal year 1999 within 6 months of receipt and review and act on 30 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

6. Review and act on 90 percent of Class 1 resubmitted original applications filed during fiscal year 1999 within 4 months of receipt and review and act on 50 percent with 2 months of receipt.

7. Review and act on 90 percent of Class 2 resubmitted original applications filed during fiscal year 1999 within 6 months of receipt.

Fiscal year 2000

1. Review and act on 90 percent of standard original NDA and PLA/BLA submissions filed during fiscal year 2000 within 12 months of receipt and review and act on 50 percent within 10 months of receipt.

2. Review and act on 90 percent of priority original NDA and PLA/BLA submissions filed during fiscal year 2000 within 6 months of receipt.

3. Review and act on 90 percent of standard efficacy supplements filed during fiscal year 2000 within 12 months of receipt and review and act on 50 percent within 10 months of receipt.

4. Review and act on 90 percent of priority efficacy supplements filed during fiscal year 2000 within 6 months of receipt.

5. Review and act on 90 percent of manufacturing supplements filed during fiscal year 2000 within 6 months of receipt and review and act on 50 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

6. Review and act on 90 percent of Class 1 resubmitted original applications filed during fiscal year 2000 within 4 months and review and act of 50 percent within 2 months of receipt.

7. Review and act on 90 percent of Class 2 resubmitted original applications filed during fiscal year 2000 within 6 months of receipt.

Fiscal year 2001

1. Review and act on 90 percent of standard original NDA and PLA/BLA submissions filed during fiscal year 2001 within 12 months and review and act on 70 percent within 10 months of receipt.

2. Review and act on 90 percent of priority original NDA and PLA/BLA submissions filed during fiscal year 2001 within 6 months of receipt.

3. Review and act on 90 percent of standard efficacy supplements filed during fiscal year 2001 within 12 months and review and act on 70 percent within 10 months of receipt.

4. Review and act on 90 percent of priority efficacy supplements filed during fiscal year 2001 within 6 months of receipt.

5. Review and act on 90 percent of priority efficacy supplements filed during fiscal year 2001 within 6 months of receipt and review and act on 70 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

6. Review and act on 90 percent of Class 1 resubmitted original applications filed during fiscal year 2001 within 4 months of receipt and review and act on 70 percent within 2 months of receipt.

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

Fiscal year 2002

1. Review and act on 90 percent of standard original NDA and PLA/BLA submissions filed during fiscal year 2001 within 10 months of receipt.

2. Review and act on 90 percent of priority original NDA and PLA/BLA submissions filed during fiscal year 2002 within 6 months of receipt.

3. Review and act on 90 percent of standard efficacy supplements filed during fiscal year 2002 within 10 months of receipt.

4. Review and act on 90 percent of priority efficacy supplements filed during fiscal year 2002 within 6 months of receipt.

5. Review and act on 90 percent of manufacturing supplements filed during fiscal year 2002 within 6 months of receipt and review and act on 90 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

6. Review and act on 90 percent of Class 1 resubmitted original applications filed during fiscal year 2002 within 2 months of receipt.

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

These review goals are summarized in the following tables:

ORIGINAL NDAs/BLAs/PLAs AND EFFICACY SUPPLEMENTS

Submission cohort	Standard	Priority
Fiscal year:		
1998	90 pct. in 12 mos	90 pct. in 6 mos.
1999	30 pct. in 10 mos	90 pct. in 6 mos.
	90 pct. in 12 mos	
2000	50 pct. in 10 mos	90 pct. in 6 mos.
	90 pct. in 12 mos	
2001	70 pct. in 10 mos	90 pct. in 6 mos.
	90 pct. in 12 mos	
2002	90 pct. in 10 mos	90 pct. in 6 mos.

MANUFACTURING SUPPLEMENTS

Submission cohort	Manufacturing supplements that—	
	do not require prior approval [1]	Do require prior approval
Fiscal year:		
1998	90 pct. in 6 mos	90 pct. in 6 mos.
1999	90 pct. in 6 mos	30 pct. in 4 mos.
		90 pct. in 6 mos.
2000	90 pct. in 6 mos	50 pct. in 4 mos.
		90 pct. in 6 mos.
1901	90 pct. in 6 mos	70 pct. in 4 mos.
		90 pct. in 6 mos.
1902	90 pct. in 6 mos.	90 pct. in 4 mos.

Changes being effected or 30-day supplements.

RESUBMISSION OF ORIGINAL NDAs/BLAs/PLAs

Submission cohort	Class 1	Class 2
Fiscal years:		
1998	90 pct. in 6 mos	90 pct. in 6 mos.
	30 pct. in 2 mos	
1999	90 pct. in 4 mos	90 pct. in 6 mos.
	50 pct. in 2 mos	
2000	90 pct. in 4 mos	90 pct. in 6 mos.
	70 pct. in 2 mos	
2001	90 pct. in 2 mos	90 pct. in 6 mos.
2002	90 pct. in 2 mos	90 pct. in 6 mos.

II. NEW MOLECULAR ENTITY (NME) PERFORMANCE GOALS

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.

For biological products, for purposes of this performance goal, all original BLAs/PLAs 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 meeting (i.e., a scheduled face-to-face, teleconference, or video conference) 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 70% of requests (based on request receipt cohort year) starting in FY 1999; 80% in FY 2000; and 90% in subsequent fiscal years.

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.

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

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

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

2. Performance goal: 70% of meetings are held within the time frame (based on cohort year of request) starting in FY 1999; 80% in FY 2000; and 90% in subsequent fiscal years.

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: 70% of minutes are issued within 30 calendar days of date of meeting (based on cohort year of meeting) starting in FY 1999; 80% in FY 2000; and 90% in subsequent fiscal years.

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 or C meetings and at least 1 month in advance of the scheduled meeting for Type B 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.

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

75% of such responses are provided within 30 calendar days of the Agency's receipt of the sponsor's response starting in FY 98 (cohort of date of receipt) and 90% in subsequent fiscal years.

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 divisional level (including a request for reconsideration by the Division 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

70% of such answers are provided within 30 calendar days of the Center's receipt of the written appeal starting in FY 1999; 80% in FY 2000, and 90% in subsequent fiscal years.

C. Conditions

1. Sponsors should first try to resolve the procedural or scientific issue at the Division level. If it cannot be resolved at that level, it should be appealed to the Office Director level (with a copy to the Division Director) and then, if necessary, to the Deputy Center Director or Center Director (with a copy to the Office Director).

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 deny or grant 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 cased, 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 cased, 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 goals

60 percent of special protocols assessments and agreement requests completed and returned to sponsor within time frames (based on cohort year of request) starting in FY 1999; 70 percent in FY 2000; 80 percent in FY 2001; and 90 percent FY 2002.

VII. ELECTRONIC APPLICATIONS AND SUBMISSIONS

The Agency shall develop and update its information management infrastructure to allow, by fiscal year 2002, the paperless receipt and processing of INDs and human drug applications, as defined in PDUFA, and related submissions.

VIII. ADDITIONAL PROCEDURES

A. Simplification of action letters

To simplify regulatory procedures, the CBER and the 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 an ''information request'' (IR) letter when each discipline has finished its initial review of its section of the pending application.

IX. 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 submitted within three months of the goal date extends the goal date by three months.

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 by the agency as fitting the Class 1 category);
9. Other minor clarifying information (determined by the Agency as fitting the Class 1 category); and
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 item but 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).

G. 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/PLA/BLA meeting. Each requestor should usually only request 1 each of these Type B meetings for each potential application (NDA/PLA/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.

Mr. BURR of North Carolina. Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume. This is primarily a technical corrections bill to correct some provisions of the FDA reform bill that this House passed by voice on Sunday. This correction resolution does not change any of the underlying policies of the FDA legislation, nor does it make any new substantive policy changes.

Mr. Speaker, I ask for House support.

Mr. RUSH. Mr. Speaker, I am proud to speak today in support of the conference report to pass FDA reform legislation.

During the markup in the Commerce Committee of H.R. 1411, the Drug and Biological Products Modernization Act of 1997, I offered an amendment to the bill to ensure that women and members of minority and ethnic groups would be adequately represented in clinical trials of new drugs that are submitted to the Food and Drug Administration [FDA] for approval.

This amendment specifically directs the Secretary of Health and Human Services to consult with the National Institute of Health [NIH] to review and develop guidelines on the inclusion of women and minorities in clinical trials.

This important amendment was unanimously adopted by the committee by voice vote.

In passing H.R. 1411, the Committee engaged in a vigorous debate about the respective roles of government and the industry. We have heard a lot about how we must not sacrifice the public health and consumer safety by allowing faster approval of new drugs. In the same spirit, we must not lose sight of equity issues.

I congratulate Members on both sides of the aisle for working hundreds of hours to craft this bill. And staff, on both sides, are to be commended for their dedication to fine-tuning this landmark legislation.

I look forward to working with Members of Congress, the administration, and medical and consumer groups to help expand the inclusion of women and minorities in clinical trials.

I rise in strong support of the conference report and urge all Members to vote ''yes'' on this bill.

Mr. BROWN of Ohio. Mr. Speaker, I yield back the balance of my time.

Mr. BURR of North Carolina. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from North Carolina [Mr. BURR] that the House suspend the rules and agree to the concurrent resolution, House Concurrent Resolution 196.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the concurrent resolution was agreed to.

A motion to reconsider was laid on the table.

AMENDING CONSOLIDATED OMNIBUS BUDGET RECONCILIATION ACT OF 1985 RELATING TO CUSTOMS USER FEES

Mr. SHAW. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3034) to amend section 13031 of the Consolidated Omnibus Budget Reconciliation Act of 1985, relating to customs user fees, to allow the use of such fees to provide for customs inspectional personnel in connection with the arrival of passengers in Florida, and for other purposes.

The Clerk read as follows:

H.R. 3034

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

SECTION 1. FUNDS FOR CUSTOMS INSPECTION PERSONNEL.

(a) ACCESS TO CUSTOMS USER FEE ACCOUNT.—Section 13031(f)(3)(A) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (19 U.S.C. 58c(f)(3)(A)), is amended—

(1) in clause (i)(V), by striking ''and'' at the end;

(2) in clause (ii)—

(A) by striking ''to make reimbursements'' and inserting ''after making reimbursements''; and

(B) by striking the period at the end and inserting '', and'', and