

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF THE TREASURY

### Office of the Comptroller of the Currency

#### 12 CFR Chap. I

[Docket No. 04–18]

### BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

#### 12 CFR Chap. II

[Docket No. R–1206]

### FEDERAL DEPOSIT INSURANCE CORPORATION

#### 12 CFR Chap. III

## DEPARTMENT OF THE TREASURY

### Office of Thrift Supervision

#### 12 CFR Chap. V

[No. 2004–35]

### Request for Burden Reduction Recommendations; Consumer Protection: Account/Deposit Relationships and Miscellaneous Consumer Rules; Economic Growth and Regulatory Paperwork Reduction Act of 1996 Review

**AGENCIES:** Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); and Office of Thrift Supervision (OTS), Treasury.

**ACTION:** Notice of regulatory review; request for comments.

**SUMMARY:** The OCC, Board, FDIC, and OTS (“we” or “the Agencies”) are reviewing our regulations to identify outdated, unnecessary, or unduly burdensome regulatory requirements pursuant to the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (EGRPRA). Today, we request your comments and suggestions on ways to reduce burden in rules we have

categorized as Consumer Protection: Account/Deposit Relationships and Miscellaneous Consumer Rules, consistent with our statutory obligations. All comments are welcome. We specifically invite comment on the following issues: Whether statutory changes are needed; whether the regulations contain requirements that are not needed to serve the purposes of the statutes they implement; the extent to which the regulations may adversely affect competition; the cost of compliance associated with reporting, recordkeeping, and disclosure requirements, particularly on small institutions; whether any regulatory requirements are inconsistent or redundant; and whether any regulations are unclear.

We will analyze the comments received and propose burden-reducing changes to our regulations where appropriate. Some of your suggestions for burden reduction might require legislative changes. Where legislative changes would be required, we will consider your suggestions in recommending appropriate changes to Congress.

**DATES:** Written comments must be received no later than October 18, 2004.

**ADDRESSES:** You may submit comments by any of the following methods:

*EGRPRA Web site:* <http://www.EGRPRA.gov>.

- Comments submitted at the Agencies’ joint Web site will automatically be distributed to all the Agencies upon receipt. Comments received at the EGRPRA Web site and by other means will be posted on the Web site to the extent possible.

*Individual agency addresses:* You are also welcome to submit comments to the Agencies at the following contact points (due to delays in paper mail delivery in the Washington area, commenters may prefer to submit their comments by alternative means):

*OCC:* You may submit comments, identified by [docket 0418], by any of the following methods:

- *E-mail:* [regs.comments@occ.treas.gov](mailto:regs.comments@occ.treas.gov). Include [docket 0418] in the subject line of the message.
- *Fax:* (202) 874–4448.
- *Mail:* Public Information Room, Office of the Comptroller of the Currency, 250 E Street, SW., Mailstop 1–

5, Washington, DC 20219, Attention: Docket #.

*Public Inspection:* You may inspect and photocopy comments at the Public Information Room. You can make an appointment to inspect the comments by calling (202) 874–5043.

*Board:* You may submit comments, identified by Docket Number R–1206, by any of the following methods:

- *Agency Web site:* <http://www.federalreserve.gov>. Follow the instructions for submitting comments at <http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm>.
- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *E-mail:* [regs.comments@federalreserve.gov](mailto:regs.comments@federalreserve.gov). Include docket number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

All public comments are available from the Board’s Web site at [www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm](http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm) as submitted, except as necessary for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information.

Public comments may also be viewed electronically or in paper in Room MP–500 of the Board’s Martin Building (20th and C Streets, NW.) between 9 a.m. and 5 p.m. on weekdays.

*FDIC:* You may submit comments, identified as EGRPRA burden reduction comments, by any of the following methods:

- <http://www.fdic.gov/regulations/laws/federal/propose.html>.
- *E-mail:* [comments@fdic.gov](mailto:comments@fdic.gov). Include “EGRPRA burden reduction comment” in the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m.

*Public Inspection:* You may inspect comments at the FDIC Public

Information Center, Room 100, 801 17th Street, NW., between 9 a.m. and 4:30 p.m. on business days.

**OTS:** You may submit comments, identified by "No. 2004-35" by any of the following methods:

- **E-Mail:**

[regs.comments@ots.treas.gov](mailto:regs.comments@ots.treas.gov). Include "No. 2004-35" in the subject line of the message, and provide your name and telephone number.

- **Fax:** (202) 906-6518.

- **Mail:** Regulation Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

- **Hand Delivery:** Comments may be hand delivered to the Guard's Desk, East Lobby Entrance, 1700 G Street, NW., from 9 a.m. to 4 p.m. on business days, Attention: Regulation Comments, Chief Counsel's Office.

**Public Inspection:** OTS will post comments and the related index on the OTS Internet site at <http://www.ots.treas.gov>. In addition, you may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment for access, call (202) 906-5922, send an e-mail to [public.info@ots.treas.gov](mailto:public.info@ots.treas.gov), or send a fax to (202) 906-7755. (Please identify the material you would like to inspect to assist us in serving you.)

**FOR FURTHER INFORMATION CONTACT:**

**OCC:**

- **Stuart Feldstein**, Assistant Director, Legislative and Regulatory Activities Division, (202) 874-5090.

- **Heidi Thomas**, Special Counsel, Legislative and Regulatory Activities Division, (202) 874-5090.

- **Lee Walzer**, Counsel, Legislative and Regulatory Activities Division, (202) 874-5090.

**Board:**

- **Patricia A. Robinson**, Managing Senior Counsel, Legal Division, (202) 452-3005.

- **Michael J. O'Rourke**, Counsel, Legal Division, (202) 452-3288.

- **John C. Wood**, Counsel, Division of Consumer and Community Affairs, (202) 452-2412.

- **Arleen Lustig**, Supervisory Financial Analyst, Division of Banking Supervision and Regulation, (202) 452-5259.

- For users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263-4869.

**FDIC:**

- **Claude A. Rollin**, Special Assistant to the Vice Chairman, (202) 898-8741.

- **Steven D. Fritts**, Associate Director, Division of Supervision and Consumer Protection, (202) 898-3723.

- **Ruth R. Amberg**, Senior Counsel, Legal Division, (202) 898-3736.

- **Thomas Nixon**, Counsel, Legal Division, (202) 898-8766.

**OTS:**

- **Robyn Dennis**, Manager, Thrift Policy, Supervision Policy, (202) 906-5751.

- **Josephine Battle**, Program Analyst, Thrift Policy, Supervision Policy, (202) 906-6870.

- **Karen Osterloh**, Special Counsel, Regulations and Legislation Division, Chief Counsel's Office, (202) 906-6639.

**SUPPLEMENTARY INFORMATION:**

**I. Overview of the EGRPRA Review and the Steps Taken So Far**

The Agencies<sup>1</sup> are asking for your comments and suggestions on ways in which we can reduce regulatory burdens consistent with our statutory obligations. Today, we request your input to help us identify which regulatory requirements in the category "Consumer Protection: Account/Deposit Relationships and Miscellaneous Consumer Rules" are outdated, unnecessary, or unduly burdensome. We list the rules in this category in a chart at the end of this notice. Please send us your recommendations at our Web site, <http://www.EGRPRA.gov>, or to one of the listed addresses.

Today's request for comment is the third notice in our multi-year review of regulations for burden reduction required by section 2222 of EGRPRA.<sup>2</sup> We described the EGRPRA review's requirements in our first EGRPRA notice. In summary, EGRPRA requires us to:

- Categorize our regulations by type.
- Publish the regulations by category to request comments on which regulations contain requirements that are:
  - Outdated,
  - Unnecessary, or
  - Unduly burdensome.
- Publish a summary of those comments.
- Eliminate unnecessary regulations to the extent appropriate.
- Report to Congress:
- Summarizing the significant issues raised and their relative merits
- Analyzing whether legislative change is required to reduce burden.

The first publication cycle must be complete by September 2006.

<sup>1</sup> The National Credit Union Administration has participated in planning the EGRPRA review but has issued, and will issue, requests for comment separately.

<sup>2</sup> Public Law 104-208, Sept. 30, 1996, 12 U.S.C. 3311. We published our first notice in the **Federal Register** on June 16, 2003, at 68 FR 35589. We published our second notice on January 21, 2004, at 69 FR 2852. You may view the notices at our Web site: <http://www.EGRPRA.gov>.

We have identified 13 categories of rules to implement our EGRPRA review. The categories are: Applications and Reporting; Banking Operations; Capital; Community Reinvestment Act; Consumer Protection: Lending Related Rules; Consumer Protection: Account/Deposit Relationships and Miscellaneous Consumer Rules; Directors, Officers and Employees; International Operations; Money Laundering; Powers and Activities; Rules of Procedure; Safety and Soundness; and Securities. You may see the categories and the rules placed within them at our Web site <http://www.EGRPRA.gov>.

We previously requested public comment about possible burden reduction in four categories of rules. Our June 16, 2003, notice requested comment on three categories: Applications and Reporting, Powers and Activities, and International Operations. Our January 21, 2004, notice requested comment on Consumer Protection: Lending Related Rules. Today, we request comment on Consumer Protection: Account/Deposit Relationships and Miscellaneous Consumer Rules.

We plan to publish one or more categories of rules approximately every six months between 2003 and 2006 and provide a 90-day comment period for each publication. As noted earlier, we must publish all our covered categories of rules for comment and review them by the end of September 2006.

In addition to soliciting written comments, we held banker outreach meetings in Orlando, St. Louis, Denver, San Francisco, New York City, Nashville and Seattle to hear directly from the industry about ways the Agencies could reduce regulatory burden. More than 300 representatives from the industry have attended the outreach meetings. On February 20, 2004, the Agencies also held a conference in the Washington, DC area for consumer groups to obtain their input on regulatory burden reduction. Another consumer group meeting was held in San Francisco on June 24, 2004. These meetings have helped focus our regulatory burden reduction efforts. We anticipate holding additional outreach events this year. You may learn more about the meetings and related recommendations at our EGRPRA Web site (<http://www.EGRPRA.gov>).

We received 19 comments in response to the first notice and over 590 to the second notice. The Agencies appreciate the response to our notices and the outreach meetings. The written comments and remarks at the meetings came from individuals, banks, savings

associations, holding companies, industry trade groups, and consumer and community groups. You may view the comments at our EGRPRA Web site (<http://www.EGRPRA.gov>). We are actively reviewing the feedback received about specific ways to reduce regulatory burden, as well as conducting our own analyses.

On May 12, 2004, FDIC Vice Chairman John M. Reich testified about burden reduction before the Subcommittee on Financial Institutions and Consumer Credit of the House Committee on Financial Services. On June 22, 2004, Agency and industry leaders testified about regulatory reform before the Senate Committee on Banking, Housing and Urban Affairs. Agency leaders included Federal Reserve Board Governor Donald Kohn, FDIC Vice Chairman John M. Reich, NCUA Chairman JoAnn Johnson, OCC First Senior Deputy Comptroller and Chief Counsel Julie L. Williams, and OTS Chief Counsel John Bowman. We will continue to post information about our burden reduction efforts at our Web site.

## **II. Request for Comment on Consumer Protection: Account/Deposit Relationships and Miscellaneous Consumer Rules**

Today, we are asking the public to identify the ways in which the Consumer Protection: Account/Deposit Relationships and Miscellaneous Consumer Rules may be outdated, unnecessary, or unduly burdensome. We chose this category for publication relatively early in the series of requests for comment based on earlier comments from some industry representatives that the requirements imposed by the consumer protection regulations are among the most burdensome. As shown

on the chart at the end of this notice, there are 11 regulations in this category.

We encourage comments that address not only individual rules or requirements but also pertain to certain product lines. For example, in the case of a particular deposit product, are any disclosure requirements under one regulation inconsistent with or duplicative of requirements under another regulation? Do the rules require that you keep unnecessary records? A product line approach is consistent with EGRPRA's focus on how rules interact, and may be especially helpful in exposing redundant or potentially inconsistent regulatory requirements. We recognize that commenters using a product line approach may want to make recommendations about rules that are not in our current request for comment. They should do so since we designed the EGRPRA categories to stimulate creative approaches rather than limiting them.

*Specific issues to consider:* While all comments are welcome, we specifically invite comment on the following issues:

*A. Need for statutory change.* (1) Do any statutory requirements underlying the rules impose unnecessary, redundant, conflicting or unduly burdensome requirements? (2) Are there less burdensome alternatives?

*B. Need and purpose of the regulations.* (1) Are the regulations consistent with the purposes of the statutes that they implement? (2) Have circumstances changed so that a rule is no longer necessary? (3) Do changes in the financial products and services offered to consumers suggest a need to revise certain regulations (or statutes)? (4) Do any of the regulations impose compliance burdens not required by the statutes they implement?

*C. General approach/flexibility.* (1) Would a different general approach to regulating achieve statutory goals with less burden? (2) Do any of these rules impose unnecessarily inflexible requirements?

*D. Effect of the regulations on competition.* Do any of the regulations or statutes create competitive disadvantages for insured depository institutions compared to the rest of the financial services industry or competitive disadvantages for one type of insured depository institution over another?

*E. Reporting, recordkeeping and disclosure requirements.* (1) Which reporting, recordkeeping, or disclosure requirements impose the most compliance burdens? (2) Are any of the reporting or recordkeeping requirements unnecessary to demonstrate compliance with the law?

*F. Consistency and redundancy.* (1) Are any of the requirements under one regulation inconsistent with or duplicative of requirements under another regulation? (2) If so, are the inconsistencies not warranted by the purposes of the regulations?

*G. Clarity.* Are any of the regulations drafted unclearly?

*H. Burden on small insured institutions.* We have particular interest in minimizing burden on small insured institutions (those with assets of \$150 million or less). How could we amend these rules to minimize adverse economic impact on small insured institutions?

The Agencies appreciate the efforts of all interested parties to help us eliminate outdated, unnecessary, or unduly burdensome regulatory requirements.

**BILLING CODE** 4810-33-P; 6210-01-P; 6714-01-P; 6720-01-P

**Rules for which we are requesting comment now**  
**Consumer Protection: Account / Deposit Relationships and Miscellaneous Consumer Rules**

| Subject                                                                         | National Banks            | State Member Banks                  | State Non-Member Banks    | Thriffs                   | Holding Companies Bank <sup>3</sup><br>-----<br>Thrift |
|---------------------------------------------------------------------------------|---------------------------|-------------------------------------|---------------------------|---------------------------|--------------------------------------------------------|
| <b>Consumer Protection: Account/Deposit Relationships &amp; Miscellaneous</b>   |                           |                                     |                           |                           |                                                        |
| <b>Interagency Regulations</b>                                                  |                           |                                     |                           |                           |                                                        |
| Consumer Protection in Sales of Insurance                                       | 12 CFR Part 14            | 12 CFR Part 208, Subpart H [Reg. H] | 12 CFR Part 343           | 12 CFR Part 536           |                                                        |
| Privacy of Consumer Financial Information                                       | 12 CFR Part 40            | 12 CFR Part 216 [Reg. P]            | 12 CFR Part 332           | 12 CFR Part 573           | 12 CFR Part 216 [Reg. P]<br>-----                      |
| Prohibition Against Use of Interstate Branches Primarily for Deposit Production | 12 CFR Part 25, Subpart E | 12 CFR 208.7 [Reg. H]               | 12 CFR Part 369           |                           | 12 CFR 208.7 [Reg. H]<br>-----                         |
| Safeguarding Customer Information                                               | 12 CFR Part 30, App. B    | 12 CFR Part 208, App. D-2 [Reg. H]  | 12 CFR Part 364, App. B   | 12 CFR Part 570, App. B   | 12 CFR 225.4(h); 12 CFR Part 225, App. F<br>-----      |
| <b>Board Regulations</b>                                                        |                           |                                     |                           |                           |                                                        |
| Electronic Fund Transfers                                                       | 12 CFR Part 205 [Reg. E]  | 12 CFR Part 205 [Reg. E]            | 12 CFR Part 205 [Reg. E]  | 12 CFR Part 205 [Reg. E]  |                                                        |
| Truth in Savings                                                                | 12 CFR Part 230 [Reg. DD] | 12 CFR Part 230 [Reg. DD]           | 12 CFR Part 230 [Reg. DD] | 12 CFR Part 230 [Reg. DD] |                                                        |
| <b>FDIC Regulations</b>                                                         |                           |                                     |                           |                           |                                                        |
| Advertisement of Membership                                                     | 12 CFR Part 328           | 12 CFR Part 328                     | 12 CFR Part 328           | 12 CFR Part 328           |                                                        |
| Deposit Insurance Coverage                                                      | 12 CFR Part 330           | 12 CFR Part 330                     | 12 CFR Part 330           | 12 CFR Part 330           |                                                        |
| Notification of Changes of Insured Status                                       | 12 CFR Part 307           | 12 CFR Part 307                     | 12 CFR Part 307           |                           |                                                        |
| <b>OTS Regulations</b>                                                          |                           |                                     |                           |                           |                                                        |
| Advertising                                                                     |                           |                                     |                           | 12 CFR 563.27             |                                                        |
| Tying Restriction Exception                                                     |                           |                                     |                           | 12 CFR 563.36             | -----<br>12 CFR 563.36                                 |

<sup>3</sup> Foreign banking organizations that conduct banking operations in the U.S., either directly through branches and agencies or indirectly through U.S. bank subsidiaries or commercial lending company subsidiaries, generally are subject to the same regulatory regime as domestic bank holding companies.

BILLING CODE 4810-33-C; 6210-01-C; 6714-01-C; 6720-01-C

Dated: July 14, 2004.

**John D. Hawke, Jr.,**

*Comptroller of the Currency.*

By order of the Board of Governors of the Federal Reserve System on July 6, 2004.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

Dated in Washington, DC, this 28 day of June, 2004.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

**Valerie J. Best,**

*Assistant Executive Secretary.*

Dated: June 24, 2004.

**James E. Gilleran,**

*Director, Office of Thrift Supervision.*

[FR Doc. 04-16401 Filed 7-19-04; 8:45 am]

BILLING CODE 4810-33-P; 6210-01-P; 6714-01-P; 6720-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 312, 314, 600, and 601

[Docket No. 2004N-0267]

#### Applications for Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend our regulations on new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for approval to market new drugs and generic drugs. We propose to discontinue the use of approvable letters and not approvable letters when taking action on marketing applications. Instead, we intend to use complete response letters to indicate that the review cycle is complete and that the application is not ready for approval. We also are proposing to revise the regulations on extending the review cycle due to the submission of an amendment to an unapproved application and starting a new cycle after a resubmission following receipt of a complete response letter. In addition, we are proposing to add to the regulations on biologics license applications (BLAs) a provision on the issuance of complete response letters to BLA applicants. We are taking these actions to implement the user fee performance goals referenced in the

Prescription Drug User Fee Amendments of 2002 that address procedures and establish target timeframes for reviewing human drug applications.

**DATES:** Submit written or electronic comments by October 18, 2004. See section VIII of this document for the proposed effective date of a final rule based on this document.

**ADDRESSES:** You may submit comments, identified by [Docket No. 2004N-0267], by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web Site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: [fdadockets@oc.fda.gov](mailto:fdadockets@oc.fda.gov). Include [Docket No. 2004N-0267] in the subject line of your e-mail message.
- Fax: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and [Docket No. 2004N-0267] for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/dockets/ecomments>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Request for Comments" heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/dockets/ecomments> and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Brian L. Pendleton, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5523.

## SUPPLEMENTARY INFORMATION:

### I. Background

#### A. User Fee Performance Goals and Complete Response Letters

In conjunction with the Prescription Drug User Fee Act of 1992 (PDUFA) (Public Law 102-571), we committed to meet certain goals for reviewing and acting on human drug applications, as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379g(1)). For example, we promised that by September 30, 1997, we would review and act on at least 90 percent of standard NDAs within 12 months after the submission date (H. Rep. No. 895, 102d Cong., 2d. sess. 32 (1992) (letter from David A. Kessler, M.D., Commissioner of Food and Drugs, to Representatives John Dingell and Norman Lent, House Committee on Energy and Commerce (September 14, 1992))).

FDA's drug application review performance goals were revised with the enactment of the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115) (the user fee provisions of this act are known as "PDUFA II"). The goals were further revised in conjunction with the enactment of the Prescription Drug User Fee Amendments of 2002 (PDUFA III), set forth in title V, subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). Section 502 of PDUFA III states that user fees will be dedicated to expediting the drug development process and the process for the review of human drug applications in accordance with the new performance goals, which are set forth in an enclosure to letters from Tommy Thompson, Secretary of Health and Human Services, to the Chairman of the House Committee on Energy and Commerce and the Ranking Member of the Senate Committee on Health, Education, Labor and Pensions (June 4, 2002) (Goals Letter).

Under the user fee performance goals, the term "review and act on" is defined as the issuance of a complete action letter after the complete review of a complete application that we have accepted for filing (Goals Letter at 15). An action letter, if not an approval, states the specific deficiencies of the application, and where appropriate, the actions necessary to place the application in condition for approval (id.).

As part of the user fee performance goals (first in PDUFA II and again in PDUFA III), FDA's Center for Drug Evaluation and Research (CDER) and