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For Internet E-Mail submittal, comments should be submitted to "comment.rm@ferc.fed.us" in the following format. On the subject line, specify Docket No. RM99-10-000. In the body of the E-Mail message, include the name of the filing entity; the software and version used to create the file, and the name and telephone number of the contact person. Attach the comment to the E-Mail in one of the formats specified above. The Commission will send an automatic acknowledgment to the sender's E-Mail address upon receipt. Questions on electronic filing should be directed to Brooks Carter at 202-501-8145, E-Mail address brooks.carter@ferc.fed.us.

Commenters should take note that, until the Commission amends its rules and regulations, the paper copy of the filing remains the official copy of the document submitted. Therefore, any discrepancies between the paper filing and the electronic filing or the diskette will be resolved by reference to the paper filing.

All written comments will be placed in the Commission's public files and will be available for inspection in the Commission's Public Reference Room at 888 First Street, N.E., Washington, D.C. 20426, during regular business hours. Additionally, comments may be viewed, printed, or downloaded remotely via the Internet through FERC's Homepage using the RIMS or CIPS links. RIMS contains all comments but only those comments submitted in electronic format are available on CIPS. User assistance is available at 202-208-2222, or by E-Mail to rimsmaster@ferc.fed.us.

David P. Boergers,
Secretary.

Appendix A—Topics for Discussion at Form 6 Technical Conference September 8, 1999

Form 6 General Information, Instructions, and Definitions (Pages i—iii)

- What information, instructions, and definitions should be included, eliminated, revised, and consolidated?

Form 6 Instructions

- Where are there interpretation problems with the Form 6 instructions? For example, categorizing expenses between operations and maintenance expense, defining system property, defining Statement of Cash Flows line item requirements, and calculating cost of service.

- Identify by schedule and instruction where more clarification is needed.
- Define type and detail of instruction needed.

Form 6 Schedules

- What GAAP updates should be made? For example, updating the "Analysis of Federal Income and Other Taxes Deferred" Schedule from APB 11 to FASB 109.

- Are there items that should be included, eliminated, revised, and consolidated in each Form 6 schedule?

- Identify by schedule, column, and line item where changes are needed.
- Define type and detail of change needed.

Conforming Form 6 Changes to the Oil Regulations

- What changes need to be made to conform the instruction and schedule changes outlined above to the oil regulations?

- Identify the part and section of the regulations that need to be changed.
- Define type and detail of change needed.

Form 6 Alternatives

- Are there other alternatives to filing the Form 6? For example, filing GAAP financial statements certified by the external accountants and supplemental schedules containing the information FERC needs to regulate its jurisdictional companies.

Form 6 Electronic Filing

- What format should be used to prepare the Form 6 (e.g., use the same format used to prepare the Form 1 or Form 2)?
- How should the electronic Form 6 be tested?

[FR Doc. 99-20110 Filed 8-4-99; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket Nos. 99N-0193 and 99D-0529]

Changes to an Approved NDA or ANDA; Proposed Rule and Draft Companion Guidance; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss proposed amendments to its regulations on postapproval changes to the chemistry, manufacturing, and controls of approved drugs, and a draft companion guidance. FDA is inviting interested parties, including industry, health professionals, patients, and patient advocacy groups to present their perspectives on the proposed amendments and the draft companion guidance.

DATES: The meeting will be held on Thursday, August 19, 1999, from 9 a.m.

to 5 p.m. Registration and requests to make an oral presentation should be received by Monday, August 13, 1999.

ADDRESSES: The meeting will be held at the Hilton Hotel, 620 Perry Pkwy., Gaithersburg, MD. To register and request time for an oral presentation, send or fax written material to the listed contact person.

FOR FURTHER INFORMATION CONTACT: Susan C. Lange, Office of New Drug Chemistry (HFD-800), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5918, FAX 301-594-0746.

SUPPLEMENTARY INFORMATION: Section 116 of the Food and Drug Administration Modernization Act of 1997 provides for the revision of § 314.70 (21 CFR 314.70) of FDA regulations concerning postapproval changes to the chemistry, manufacturing, and controls of approved drugs. In the **Federal Register** of June 28, 1999 (64 FR 34608), the agency published a proposed rule entitled "Supplements and Other Changes to an Approved Application," proposing amendments to § 314.70. The comment period for the proposed rule closes on September 13, 1999 (Docket No. 99N-0193). In the same issue of the **Federal Register** (64 FR 34660), the agency announced the availability of a draft guidance for industry entitled "Changes to an Approved NDA or ANDA." The comment period for the draft guidance closes on August 27, 1999 (Docket No. 99D-0529). To ensure broad public input on the proposed rule and the draft guidance, the agency is holding a public meeting on the proposed amendments to § 314.70 and the draft guidance for industry.

To provide a framework for presentations, discussions of revisions to § 314.70 will be organized according to the following sections in the proposed regulation: (1) Section 314.70(a)—Changes to an approved application; (2) § 314.70(b)—Changes requiring a prior approval supplement; (3) § 314.70(c)—Changes being effected supplement; (4) § 314.70(d)—Changes for description in an annual report; and (5) § 314.70(e)—Protocols.

The presentation topics for the draft guidance will be organized as follows: (1) Assessing the effect of manufacturing changes; (2) components and composition; (3) sites; (4) manufacturing process; (5) specifications; (6) package; (7) labeling; (8) miscellaneous changes; and (9) multiple changes.

When submitting a request for an oral presentation at the August 19, 1999, meeting, please specify your

presentation topic. The time allowed for each presenter will depend on the number of presentation requests.

Registration information (including name, title, firm name, address, telephone, and fax number) and requests for presentation (including specific topic) should be submitted to the listed contact person by Friday, August 13, 1999. Space is limited, therefore, interested parties are encouraged to register early. Special accommodations due to disability should be submitted at least 7 days in advance.

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: July 28, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99-20088 Filed 8-4-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 375

Marketable Treasury Securities Redemption Operations

AGENCY: Bureau of the Public Debt, Fiscal Service, Department of the Treasury.

ACTION: Proposed rule.

SUMMARY: The Department of the Treasury ("Treasury", "We", or "Us") is publishing for comment proposed rules setting out the terms and conditions by which we may redeem outstanding, unmaturing marketable Treasury securities. While we have not decided to conduct redemption operations, we are publishing this proposed rule to obtain comments on the mechanism by which we might conduct such operations. By establishing the mechanism in advance, we would be able to conduct redemption operations in a more timely and efficient way should such a decision be made.

We would establish a new part in the Code of Federal Regulations for this purpose. The proposed rules describe a process by which an entity may submit competitive offers to sell us securities. The proposed rules also describe how we would announce the redemption operation results and the requirements for delivering securities to us and receiving payment.

Redemption operations would help us better manage our financing needs, promote more efficient capital markets, and may lower financing costs for taxpayers.

DATES: Submit comments on or before October 4, 1999.

ADDRESSES: You may send us hardcopy comments at: Government Securities Regulations Staff, Bureau of the Public Debt, 999 E Street NW., Room 315, Washington, DC 20239-0001. You may also send us comments by e-mail at govsecreg@bpd.treas.gov. When sending comments by e-mail, please use an ASCII file format and provide your full name and mailing address. Comments received will be available for public inspection and downloading from the Internet and for public inspection and copying at the Treasury Department Library, FOIA Collection, Room 5030, Main Treasury Building, 1500 Pennsylvania Avenue, NW., Washington, DC 20220. To visit the library, call (202) 622-0990 for an appointment.

This proposed amendment is also available for downloading from Public Debt's web site at the following address: www.publicdebt.treas.gov.

FOR FURTHER INFORMATION CONTACT: Lori Santamarena (Acting Executive Director) or Chuck Andreatta (Senior Financial Advisor), Bureau of the Public Debt, Government Securities Regulations Staff, (202) 691-3632.

SUPPLEMENTARY INFORMATION:

I. Background

The government's improved fiscal position has caused Treasury's borrowing needs to decline significantly, and we have been adjusting the government's borrowing program accordingly. Our adjustments to date have distributed the required cuts in borrowing across various maturities and sectors of the federal debt. In this environment, we began examining the concept of purchasing outstanding Treasury securities in the market. No decisions have been made to use a debt buy-back program, but having the infrastructure available to be able to use this tool would provide Treasury additional flexibility.

Debt buy-backs could provide us with greater flexibility to manage the government's debt and to respond to our improved fiscal condition. First, buy-backs could enhance market liquidity by allowing us to maintain regular issuance of new benchmark securities across the maturity spectrum, in greater volume than otherwise. Over the long term, this enhanced liquidity could reduce the

government's interest expense and promote more efficient capital markets.

Second, buy-backs could enhance our ability to exert control over the maturity structure of the debt. Without a debt buy-back program, further reductions in Treasury new issue sizes and frequencies could be necessary. A buy-back program, however, would provide us the option of managing the maturity structure of the debt by selectively targeting the maturities of debt to be repurchased.

Third, buy-backs could be used as a cash management tool, absorbing excess cash in periods such as late April when tax revenues greatly exceed immediate spending needs.

In addition, although not a primary reason for conducting buy-backs, we may occasionally be able to reduce the government's interest expense by purchasing "off-the-run" debt and replacing it with lower-yield "on-the-run" debt.¹

II. Analysis

In a buy-back operation (a "redemption operation" in the proposed rule), we would redeem securities by purchasing them from current owners. The most equitable method for determining redemption prices is through a process in which market participants submit competitive offers to sell particular Treasury securities to the Treasury. We welcome comments about this proposed methodology.

Under the proposal, we would announce our intention to purchase specified Treasury securities, including the approximate total amount that we want to buy, and the deadlines for offers and settlement. We would accept offers on a multiple-price basis—that is, we would determine and accept the most attractive offers and each successful offeror would receive the price at which it offered securities. We could decide to buy back less than the announced amount if market conditions warranted.

For the reasons set forth below, we propose that the entities that have a trading relationship with the Federal Reserve Bank of New York (primary dealers) be eligible to submit offers. Other entities could submit offers through the primary dealers or an intermediary that has a relationship with a primary dealer.

Restricting direct offers to primary dealers would permit us to use the

¹ A Treasury security is "on-the-run" when it is the newest security issue of its maturity (e.g., in October the two-year note issued September 30 would be "on-the-run" while the two-year note issued August 31 would be "off-the-run"). An on-the-run security is normally the most liquid issue for that maturity.