

preceding year's CPI-U, as published by the DOL. See 12 U.S.C. 1422(13)(B).

Section 7(i)(2)(B) of the Bank Act and § 918.3(a)(1) of the Finance Board regulations require the Finance Board to make similar annual adjustments to the annual compensation limits for members of the boards of directors of the Banks. See 12 U.S.C. 1427(i)(2) and 12 CFR 918.3(a).

Under the AHP regulation, the Finance Board must make three similar annual adjustments that may affect how a Bank allocates its yearly required AHP contributions. See 12 CFR 951.3(a)(1)–(2). The first annual adjustment sets the maximum dollar limit a Bank may set aside annually for the current year and the subsequent year towards homeownership set-aside programs. The second adjustment sets the maximum dollar limit a Bank may set aside annually for the current year and the subsequent year towards an additional first-time homebuyer set-aside program. The third adjustment sets the maximum dollar limit a Bank may allocate from its annual required AHP contribution for the subsequent year to the current year's competitive application program.

#### B. Calculating the Annual Adjustments

All of these annual adjustments—to the CFI asset cap, annual Bank director compensation limits, and maximum dollar limits on Bank allocations from annual required AHP contributions—reflect the percentage by which the CPI-U published for November of the preceding calendar year exceeds the CPI-U published for November of the year before the preceding calendar year (if at all). For example, the adjustments that will become effective on January 1, 2006, are based on the percentage increase in the CPI-U from November 2004 to November 2005. The Finance Board uses November data to ensure publication of the changes to the annual limits before the January 1st effective date. This practice is consistent with that of other federal agencies.

The DOL encourages use of CPI-U data that has not been seasonally adjusted in “escalation agreements” because seasonal factors are updated annually and seasonally adjusted data are subject to revision for up to 5 years following the original release. Unadjusted data are not routinely subject to revision, and previously published unadjusted data are only corrected when significant calculation errors are discovered. Accordingly, the Finance Board is using data that has not been seasonally adjusted.

The unadjusted CPI-U increased 3.5 percent between November 2004 and November 2005. Based on this change,

and effective on January 1, 2006, the Finance Board has made the following adjustments:

**CFI Asset Cap:** The CFI Asset Cap, which was \$567 million for 2005, will be \$587 million in 2006. The Finance Board arrived at the adjusted limit of \$587 million by rounding to the nearest million.

**Annual compensation limits:** The annual compensation limits for members of the Bank boards of directors will be as follows in 2006: For a Chairperson—\$29,357; for a Vice-Chairperson—\$23,486; for any other member of a Bank's board of directors—\$17,614. The Finance Board arrived at the adjusted annual compensation limits by rounding to the nearest dollar.

**Dollar limits on Bank allocations from annual required AHP contributions.** The maximum dollar limit on the amount a Bank may set aside from its annual required AHP contributions, for the current year and the subsequent year, toward homeownership set-aside programs, which was \$3.2 million in 2005, will be \$3.3 million in 2006.

The maximum dollar limit on the amount a Bank may set aside from its annual required AHP contributions towards an additional first-time homebuyer set-aside program, for the current year and subsequent year, which was \$1.6 million in 2005, will be \$1.7 million in 2006.

The maximum dollar limit on the amount a Bank may allocate from its annual required AHP contribution, for the subsequent year to the current year's competitive application program, which was \$3.2 million in 2005, will be \$3.3 million in 2006.

The Finance Board arrived at the adjusted AHP limits by rounding to the nearest \$100,000.<sup>1</sup>

Dated: December 21, 2005.

By the Federal Housing Finance Board.

**Ronald A. Rosenfeld,**  
Chairman.

[FR Doc. E5-7890 Filed 12-27-05; 8:45 am]

**BILLING CODE 6725-01-P**

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## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company

<sup>1</sup> While all adjusted limits in this Notice have been rounded to some dollar level, the calculations of new limits are based on cumulative CPI-U changes applied to the limits as they first appeared in Finance Board regulations, and hence are not distorted over time by rounding.

Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center Web site at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 20, 2006.

**A. Federal Reserve Bank of New York** (Jay Bernstein, Bank Supervision Officer) 33 Liberty Street, New York, New York 10045-0001:

1. *Bay View Capital Corporation*, San Mateo, California; to become a bank holding company by acquiring 100 percent of the voting shares of Great Lakes Bancorp, Buffalo, New York, and thereby acquiring Greater Buffalo Savings Bank, Buffalo, New York.

2. *TrustCo Bank Corp NY*, Glenville, New York; to become a bank holding company by acquiring 100 percent of the voting shares of Ballston Spa Bancorp and thereby acquire Ballston Spa National Bank, both of Ballston Spa, New York.

In connection with this application, Applicant also has applied to retain control of TrustCo Bank, Schenectady, New York, and thereby continue to engage in operating a savings and loan association, pursuant to section 225.28(b)(4)(ii) of Regulation Y.

**B. Federal Reserve Bank of Cleveland** (Cindy West, Manager) 1455 East Sixth Street, Cleveland, Ohio 44101-2566:

1. *Sky Financial Group, Inc.*, Bowling Green, Ohio; to acquire up to 9.99

percent of the voting shares of LNB Bancorp, Inc., Lorain, Ohio, and thereby indirectly acquire voting shares of the Lorain National Bank, Lorain, Ohio.

Board of Governors of the Federal Reserve System, December 22, 2005.

**Jennifer J. Johnson,**

*Secretary of the Board.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005P-0244]

#### Determination That DECADRON (Dexamethasone) Tablets, 1.5 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that DECADRON (dexamethasone) tablets, 1.5 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dexamethasone tablets, 1.5 mg.

**FOR FURTHER INFORMATION CONTACT:**

Janice L. Weiner, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98-417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

DECADRON (dexamethasone) tablets, 1.5 mg, are the subject of approved NDA 11-664 held by Merck & Co., Inc. (Merck). According to Merck's 1997 annual report, the 1.5-mg dose strength, among others, of DECADRON (dexamethasone) tablets, a synthetic adrenocortical steroid, was discontinued in 1997. In a citizen petition dated June 16, 2005 (Docket No. 2005P-0244), submitted under 21 CFR 10.30, ECR Pharmaceuticals requested that the agency determine whether DECADRON (dexamethasone) tablets, 1.5 mg, were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Merck's DECADRON (dexamethasone) tablets, 1.5 mg, were not withdrawn from sale for reasons of safety or effectiveness. FDA has reviewed its files for records concerning the withdrawal of DECADRON (dexamethasone) tablets, 1.5 mg, from sale. There is no indication that the decision not to market DECADRON (dexamethasone) tablets, 1.5 mg, commercially is a function of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for possible concerns regarding the safety or effectiveness of this drug product. FDA has found no information that would indicate that this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that for the reasons outlined previously, DECADRON (dexamethasone) tablets, 1.5 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DECADRON (dexamethasone) tablets, 1.5 mg, in the

"Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs for dexamethasone tablets, 1.5 mg, that comply with relevant legal and regulatory requirements may be approved by the agency.

Dated: December 19, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0488]

#### Animal Drug User Fee Act; Public Meeting

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

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting on the Animal Drug User Fee Act (ADUFA) to seek public comments relative to the program's overall performance and reauthorization as directed by Congress.

**Date and Time:** The public meeting will be held on February 24, 2006, from 9 a.m. to 5 p.m. Requests to make a presentation at the meeting must be received by February 10, 2006. Written comments regarding this meeting may be made by March 26, 2006, to the Division of Dockets Management (see **ADDRESSES**).

**Location:** The meeting will be held at the DoubleTree Hotel, Plaza II and III, 1750 Rockville Pike, Rockville, MD 20852. Registration is not required to attend the meeting. Parking is limited, so we recommend arriving by subway (Metro rail) if possible. The DoubleTree Hotel is accessible from the Metro rail's red line at the Twinbrook station.

**ADDRESSES:** You may submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Aleta Sindelar, Center for Veterinary