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Steven W. Thompson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

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DELAWARE RIVER BASIN COMMISSION

18 CFR Part 410

Schedule of Water Charges

AGENCY: Delaware River Basin Commission.

ACTION: Notice of proposed rulemaking and public hearing.

SUMMARY: The Delaware River Basin Commission will hold a public hearing to receive comments on proposed amendments to the Administrative Manual—Part III—Basin Regulations—Water Supply Charges to revise the schedule of water charges.

DATES: The Commission will hold a public hearing on Tuesday, April 13, 2010, beginning at 1:30 p.m. The hearing will continue until the later of 3:30 p.m. or such time as all those who wish to testify have been afforded an opportunity to do so. Written comments will be accepted until 5 p.m. on Friday, April 16, 2010.

ADDRESSES: The hearing will take place in the Goddard Room at the Commission's office building, located at 25 State Police Drive, West Trenton, New Jersey. Driving directions are available on the Commission's Web site—<http://www.drbc.net>. Please do not rely on Internet mapping services as they may not provide accurate directions to the DRBC.

Written comments may be submitted at the hearing and may also be sent as follows: via e-mail to Paula.Schmitt@drbc.state.nj.us; otherwise, to the attention of the Commission Secretary, DRBC, either by fax to (609) 883-9522; U.S. Mail to P.O. Box 7360, West Trenton, NJ 08628-0360; or delivery service to 25 State Police Drive, West Trenton, NJ 08628-0360. Regardless of the method of submission, written comments should include the name, affiliation (if any) and address of the commenter and the subject line "Schedule of Water Charges."

FOR FURTHER INFORMATION, CONTACT: Please contact Paula Schmitt at 609-477-7224 or Katharine O'Hara at 609-477-7205 with questions about the public hearing.

SUPPLEMENTARY INFORMATION:

Background. In response to the need to fund certain water supply storage facility projects, the Commission between 1964 and 1974 established a system of water supply charges pursuant to section 3.7 of the Delaware River Basin Compact. In December of 1964, it adopted Resolution 64-16A, "A Resolution to establish policy concerning water supply in federal projects authorized in the Comprehensive Plan." This resolution established a revenue stream to repay the obligations the Commission eventually assumed to purchase capacity at the federal government's Beltzville and Blue Marsh water storage facilities. The resolution specifically provided that the debt for DRBC's share of storage in these facilities would be repaid through the sale of water (or other products and services) and through an apportionment of the costs to the states benefiting from those projects. *See* Resolution No. 64-16A, adopted December 29, 1964 (adding to the Comprehensive Plan a "Section IX—Water Supply Policy", par. 3.a. and b. of which establish the described debt repayment mechanisms).

The Commission subsequently adopted Resolution No. 71-4, "A Resolution to amend and supplement the Comprehensive Plan by the addition of a new article on policy for water supply charges." This resolution established a schedule of rates for basin water withdrawals and provided that the "charges for water supplied will include all costs associated with making basin water supply available and maintaining its continued availability in adequate quantity and quality over time." Res. No. 71-4, adopted April 7, 1971, par. A.2. Resolution No. 71-4 requires the Commission to collect sufficient annual revenue to meet all annual project costs, "including debt service, operation, maintenance, replacement, reserves, and associated administrative costs." Res. No. 71-4, par. A.2.b. The Commission recognized that the waters of the basin formed a "unitary system" and thus applied the charges to water withdrawals made throughout the basin, including upstream of Commission facilities. *See* Res. No. 71-4, preamble. The unitary system is sometimes referred to as the "pooled water" theory. *See, for example, Delaware River Basin Commission v. Bucks County Water & Sewer Authority*, 641 F. 2d 1087, 1094 (3rd Cir. 1982) (citing *Borough of Morrisville v. Delaware River Basin Comm'n*, 399 F.Supp. 469, 471 (E.D. Pa. 1975), *aff'd per curiam*, 532 F.2d 745 (3d Cir. 1976)).

Resolution No. 71-4 imposed charges only on withdrawals from surface waters of the basin. In accordance with Section 15.1(b) of the Compact, it limited charges to the amounts of water withdrawn in excess of those "that could lawfully have been made without charge on the effective date of the Compact." Compact § 15.1(b).

The Commission has historically placed the revenues generated through the sale of water in an account called the "Water Supply Storage Facilities Fund" ("Storage Fund"). The Storage Fund holds funds dedicated to pay the costs of project construction, operation, maintenance, and replacement, as well as associated administrative costs. *See* Res. No. 71-4, par. A.2. The estimated balance in the Storage Fund as of June 30, 2009 was \$12.1M. A snapshot of the Storage Fund at the close of fiscal year ending July 31, 2009 shows the following: The Storage Fund received approximately \$2.6M in water sale revenue. It disbursed or incurred approximately \$2.2M in expenses, consisting of approximately \$483K in interest paid to the U.S. Treasury, \$423K in asset depreciation, \$310K for operations and maintenance of the Blue Marsh and Beltzville projects, \$86K for contractual services from the U.S. Geological Survey for operation and maintenance of stream gauges, and \$933K associated with Commission administration. The fund lost \$153K on investments (the sole Storage Fund investment loss in 35 years). The approximately \$204K difference between the annual costs and revenue is retained in the Storage Fund as a reserve against the future costs of expected significant repair to the facilities.

Historically, the Commission has not charged its full administrative cost against the Storage Fund. Periodic reviews of the charges have shown that the costs involved in Commission activities properly chargeable to the Storage Fund have exceeded the amounts actually charged for many years. To the extent that the Storage Fund has not been charged its full allocable costs, contributions by the signatory parties of the Delaware River Basin Compact (the states of Delaware, New Jersey, New York, Pennsylvania and the federal government) have made up the difference. In extremely challenging economic times, however, the signatories find themselves less capable of assuming this burden. In fiscal year 2010, an adjustment was made to better align charges to the Storage Fund with actual costs. Even absent this adjustment, the trend evident since 2008 is that retained Storage Fund earnings have leveled off.

Recent plant closures in the basin are expected to result in reductions of approximately \$500K annually (about 20 percent) in water sale revenues, while the costs of reservoir maintenance and operations, contractual services and administration continue to rise.

DRBC's Current Schedule of Water Charges. Resolution No. 71-4 provided that water rates would consist of "the weighted-average unit cost of all water stored by or on behalf of the Commission" and specified that the unit cost of all water would be determined "by dividing all of the commission's annual project cost by the net yield of the water supply in federal reservoirs authorized in the commission's Comprehensive Plan." Res. No. 71-4, par. A.2.a. Also see Res. No. 78-14, preamble.

In accordance with this formula, the current schedule of water charges was established by Resolution No. 78-14 in October of 1978, based on the unit cost of water stored by the Commission in the Beltzville and Blue Marsh reservoirs. It was codified at section 5.3.1 of the Commission's Administrative Manual—Part III—Basin Regulations—Water Supply Charges (hereinafter, "WSC"). Section 5.3.1 provides that the Commission "will from time to time, after public notice and hearing, make, amend and revise a schedule of water charges" and that until changed, the charges for water shall be \$.06 per thousand gallons for consumptive use (\$60 per million gallons) and six-tenths of a mill per thousand gallons (\$.60 per million gallons) for non-consumptive use. WSC § 5.3.1. These rates which have remain unchanged for more than 30 years, lag far behind the rates charged for raw (untreated) water by the Commission's sister agency the Susquehanna River Basin Commission (SRBC) and by the New Jersey Water Supply Authority (NJWSA) for raw water from its Raritan System.

The consumptive use rate established by SRBC in May of 1992, effective January 1, 1993, was \$140 per million gallons, nearly two-and-a-half times the current rate charged by DRBC. In June of 2008, SRBC approved a two-step increase to \$210 per million gallons effective January 1, 2009, and \$280 per million gallons (more than four-and-a-half times DRBC's current rate) effective January 1, 2010. NJWSA charged \$216 per million gallons as of July 1, 2010 and will charge \$220 per million gallons (more than three-and-a-half times DRBC's current rate) as of July 1, 2011, for raw water from its Raritan System. DRBC's proposed 2010 and 2011 rates

for consumptively used water remain well below those of its counterparts.

Proposed Rate Increase. Resolution No. 71-4 provided that "[c]osts, rates and charges will be recomputed * * * as often as necessary to reflect relevant changes in any cost components associated with sustaining specific base flows." Res. No. 71-4, par. A.2.a. At this time, in order to maintain net income to the Storage Fund and ensure financial stability to address future operating and maintenance costs, the Commission is proposing its first water charging rate increase in 32 years. Because many people find the expression of the rates confusing, the Commission also is proposing that the new rates be established per million gallons rather than per thousand.

In light of the difficult economic climate, the rate change is proposed in two stages. The proposed rates, calculated using the formula established by Resolution No. 71-4 and set forth above, are as follows: The consumptive use rate is proposed to be increased from \$60 to \$90 per million gallons effective on January 1, 2010, and from \$90 to \$120 per million gallons effective on January 1, 2011. The non-consumptive use rate is proposed to be increased from \$.60 to \$.90 per million gallons effective on January 1, 2010, and from \$.90 to \$1.20 per million gallons effective on January 1, 2011.

Even with the proposed increases, Delaware Basin water will remain inexpensive when compared to raw water in neighboring jurisdictions. Notably, the proposed 2012 rate of \$120 per million gallons for raw water consumptively used in the Delaware Basin is less than half the rate of \$280 currently in effect in the Susquehanna Basin and only a little more than half the rate of \$216 currently charged by the NJWSA for its Raritan System water, which rate will increase to \$220 effective January 1, 2011. The Commission's proposed 2012 rate is below the current (2010) rate of \$60 per million if adjusted for inflation, which would be approximately \$200 per million gallons.

No Change to Exempt Uses. No change to the list of uses exempt from charges, as set forth at WSC § 5.3.3 is proposed. The following categories of uses are currently exempt from water charges: Non-consumptive uses of less than 1,000 gallons a day and less than 100,000 gallons during any quarter (§ 5.3.3 A.); ballast water used for shipping purposes (§ 5.3.3 B.); water taken, withdrawn or diverted from streams tributary to the River Master's gauging station at Montague, New Jersey (§ 5.3.3 C.); and water taken, diverted or

withdrawn below the mouth of the Cohansy River and such proportion of water withdrawn above that point and below the mouth of the Schuylkill River as the Executive Director may determine would have no discernable effect upon the maintenance of the salt front below the mouth of the Schuylkill River (§ 5.3.3 D.).

Pamela M. Bush,

Commission Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 58, 71, 101, 170, 171, 190, 312, 511, 571, and 812

[Docket No. FDA-2008-N-0115]

RIN 0910-AC59

Reporting Information Regarding Falsification of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to require sponsors to report information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies that involve human subjects or animal subjects conducted by or on behalf of a sponsor or relied on by a sponsor. A sponsor would be required to report this information to the appropriate FDA center promptly, but no later than 45 calendar days after the sponsor becomes aware of the information. This proposal is necessary because ambiguity in the current reporting scheme has caused confusion among sponsors. The proposed rule is intended to help ensure the validity of data that the agency receives in support of applications and petitions for FDA product approvals and authorization of certain labeling claims and to protect research subjects.

DATES: Submit written or electronic comments on this proposed rule by May 20, 2010. See section V of this document for the proposed effective date of a final rule based on this document. Submit comments regarding the information collection by March 22, 2010 to OMB (see **ADDRESSES**).