02148000 WATEREE RIVER NEAR CAMDEN, SC

LOCATION.--Lat 34°14'40'', long 80°39'15'', Kershaw County, Hydrologic Unit 03050104, on downstream side of pier of downstream bridge on U.S. Highway 1, 1,500 ft downstream from Five and Twenty Creek, 4,000 ft upstream from Seaboard Coast Line Railroad bridge, 2.2 mi west of Camden, 7.4 mi downstream from Wateree Dam, and at mile 68.8.

DRAINAGE AREA.--5,070 mi^2, approximately.

WATER-DISCHARGE RECORDS

PERIOD OF RECORD.--January to December 1903 (gage heights only), October 1904 to September 1910, October 1929 to current year. Monthly discharge only for some periods, published in WSP 1303. Gage-height records collected at site 1.5 mi downstream 1891-1934, at site 830 ft upstream January 1935 to September 1942, and at present site since October 1942, are contained in reports of National Weather Service.

REVISED RECORDS.--WSP 802: 1930. WSP 952: Drainage area. WSP 1082: 1934(M). WSP 1433: 1905-10. WSP 1623: 1930-51 (monthly and yearly runoff).

GAGE.--Data collection platform. Datum of gage is 115.36 ft above NGVD of 1929. January 1903 to September 1910, nonrecording gage at site 1.5 mi downstream at datum 117.71 ft above NGVD of 1929. October 1, 1929 to September 1, 1942, recording gage at site 830 ft upstream at datum 119.36 ft above NGVD of 1929. October 1942 to September 30, 1997, recording gage at present site at datum 119.36 ft above NGVD of 1929. October 1, 1997 to September 30, 2003, recording gage at present site at datum 118.36 ft above NGVD of 1929.

REMARKS.--Records fair except for estimated daily discharges, which are poor. Flow regulated by powerplants at Wateree Reservoir (usable capacity, 2,794,000,000 ft^3).

EXTREMES FOR OUTSIDE PERIOD OF RECORD.--The flood of July 18, 1916 reached a stage of 40.4 ft, datum 117.71 ft above mean sea level, at site 1.5 mi downstream, from records of National Weather Service, discharge, 400,000 ft^3/s, from rating curve extended above 122,000 ft^3/s, as explained in footnote below.

Discharge, cubic feet per second
WATER YEAR OCTOBER 2003 TO SEPTEMBER 2004
DAILY MEAN VALUES

DAY	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP
1	2460	2630	6510	6150	8430	9360	2480	2420	1970	5640	5160	7410
2	e2230	2950	5490	5480	10900	6140	2420	2910	2140	6160	2050	9010
3	3950	2100	7330	5880	9260	5070	2450	4780	1690	3880	2730	6540
4	1870	2900	7580	6160	3610	4820	2500	3160	2240	3830	3500	2010
5	902	3060	8210	4710	5290	6250	2580	3160	1440	3910	5810	2220
6	e1340	3070	6100	7180	4040	3470	2460	2780	1800	e1170	3480	6650
7	2870	2590	4690	7000	9080	3180	2500	2460	e3320	6540	2910	14500
8	2270	2210	5840	5100	10900	2670	2360	2520	2640	8560	2120	17800
9	3200	2420	4880	5920	8920	4500	2430	2920	2810	7070	2100	19100
10	5540	4500	2650	6510	7350	2490	2400	2570	1670	3680	2450	25100
11	2630	3870	5080	3970	3890	2530	2360	2920	1460	3550	3410	36000
12	2040	3730	7450	6270	5210	2390	2650	2550	1820	2930	11700	32300
13	2580	4750	4020	5950	5180	3580	2490	2570	1610	1730	6800	29700
14	3210	4300	7220	4540	1000	2410	4410	2560	1380	1590	2540	26600
15	2840	2150	8870	4110	1260	3990	4340	2550	1840	1710	5470	23900
16	3630	3990	6660	4510	2480	4000	2850	2530	2810	4880	7910	22300
17	3430	5140	5220	4630	3050	4340	2670	3000	3900	3230	6930	21300
18	2420	6980	6630	4850	2870	4780	2420	2560	1680	2130	4470	19200
19	e1510	7880	4540	4140	6070	3630	2660	2560	2490	3250	2320	17600
20	e3360	5120	6380	7520	6580	3110	2970	2680	1410	3940	3290	16900
21	3220	3980	7270	4660	9060	2820	2950	2720	1760	4400	3640	7810
22	3330	7950	6820	4020	6570	2850	3230	1580	2250	3220	1370	5450
23	4070	7230	7670	3790	2770	3280	2570	1240	3550	2980	2460	4730
24	4390	8890	6910	2470	2560	2580	2500	2280	5420	1860	1460	5440
25	3680	9150	7630	2340	4960	2960	2390	2200	5840	1830	2720	10200
26	4250	7030	8380	5230	5760	3160	2490	2060	10300	2310	2180	14400
27	4850	6440	6030	6210	5460	3370	3180	1150	9060	2250	1940	12700
28	4430	4660	4420	3780	6610	3420	2900	1530	6180	3330	3070	12500
29	6330	7240	7830	3120	8390	3110	3230	1440	4320	3790	8140	13000
30	4570	6250	6840	1980	---	4120	2440	1650	3440	4190	4060	13700
31	2630	---	6930	1660	---	3220	---	1590	---	6210	5680	---
TOTAL	100032	145160	198080	149840	167510	117600	82280	75600	94240	115750	123870	456070
MEAN	3227	4839	6390	4834	5776	3794	2743	2439	3141	3734	3996	15200
MAX	6330	9150	8870	7520	10900	9360	4410	4780	10300	8560	11700	36000
MIN	902	2100	2650	1660	1000	2390	2360	1150	1380	1170	1370	2010
CFSM	0.64	0.95	1.26	0.95	1.14	0.75	0.54	0.48	0.62	0.74	0.79	3.00
IN.	0.73	1.07	1.45	1.10	1.23	0.86	0.60	0.55	0.69	0.85	0.91	3.35

STATISTICS OF MONTHLY MEAN DATA FOR WATER YEARS 1930 - 2004, BY WATER YEAR (WY)

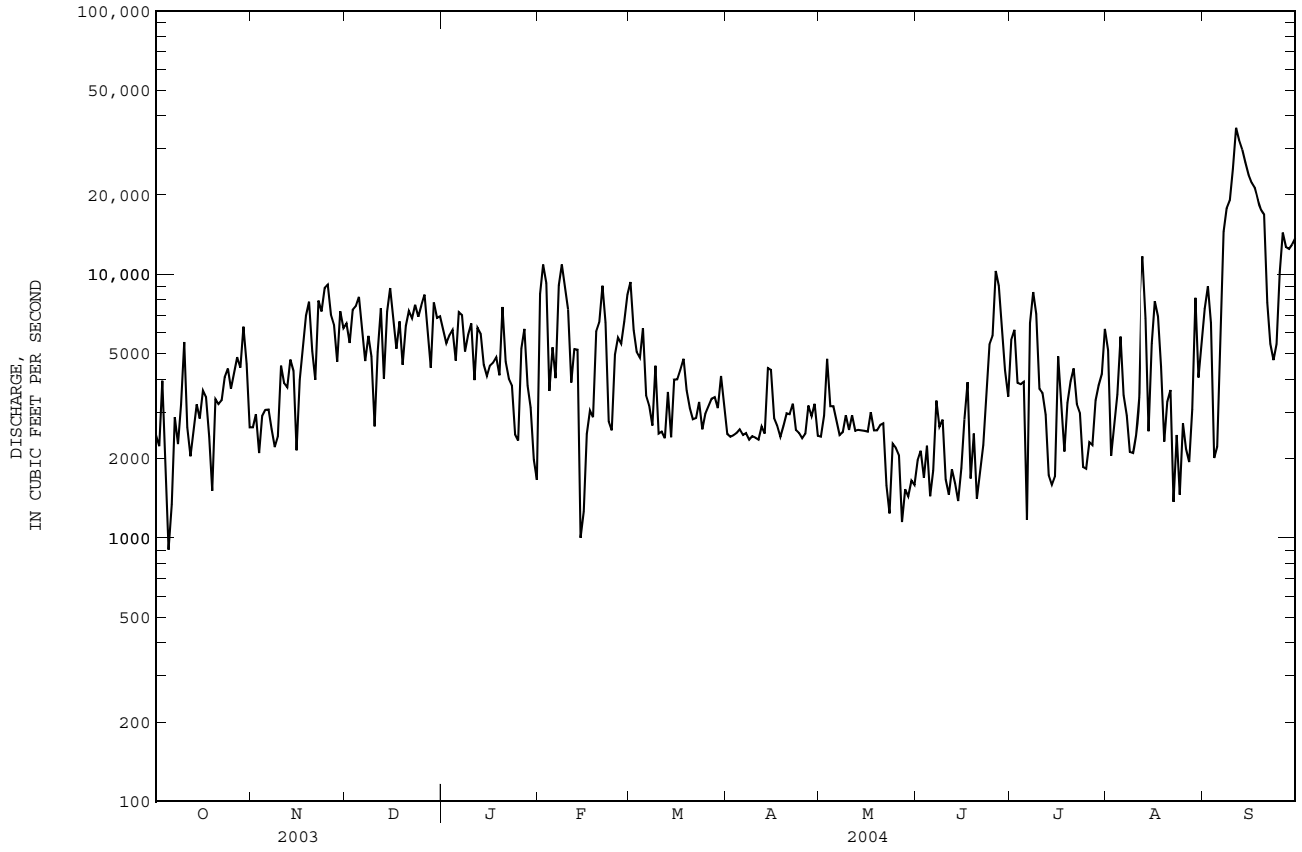
MEAN	4685	4828	5745	8358	8936	9497	8190	5513	4725	4194	4449	4167
MAX	19080	15370	14000	18530	23270	21700	28750	13280	13040	14980	12720	20430
(WY)	1965	1978	1984	1937	1960	1952	1936	2003	2003	1941	1967	1945
MIN	1095	992	1056	1803	2120	2941	1701	1022	997	656	1456	1033
(WY)	1955	1932	2002	1942	2001	1988	1986	1986	1988	1956	2002	1954

02148000 WATEREE RIVER NEAR CAMDEN, SC--Continued

SUMMARY STATISTICS	FOR 2003 CALENDAR YEAR		FOR 2004 WATER YEAR		WATER YEARS 1930 - 2004	
ANNUAL TOTAL	3455107		1826032			
ANNUAL MEAN	9466		4989		6093	
HIGHEST ANNUAL MEAN					9964	1960
LOWEST ANNUAL MEAN					1852	2002
HIGHEST DAILY MEAN	52800	Apr 12	36000	Sep 11	149000	Oct 3 1929
LOWEST DAILY MEAN	902	Oct 5	902	Oct 5	143	Sep 28 1980
ANNUAL SEVEN-DAY MINIMUM	2060	Jan 19	1630	May 26	279	Jul 1 1959
MAXIMUM PEAK FLOW			39500	Sep 11	a 366000	Aug 26 1908
MAXIMUM PEAK STAGE			29.67	Sep 11	39.70	Aug 26 1908
ANNUAL RUNOFF (CFSM)	1.87		0.984		1.20	
ANNUAL RUNOFF (INCHES)	25.35		13.40		16.33	
10 PERCENT EXCEEDS	17800		8400		12900	
50 PERCENT EXCEEDS	7670		3640		4790	
90 PERCENT EXCEEDS	2540		1980		1140	

a Site and datum then in use, from records of National Weather Service, from rating curve extended above 122,000 ft^3/s on basis of computations, by Duke Energy Corporation, of peak flow of 382,000 ft^3/s over dam at Rocky Creek Reservior.

e Estimated



Improving Generic Drug Review Performance
Generic Drug Budget Authority: +5,561,000; 13 FTE
Generic Drug User Fees: +$15,701,000; 34 FTE (First Year)

1. Why is this initiative necessary?

The number of generic drug applications submitted to FDA has been rising exponentially. During the past six years, applications increased by 158 percent, rising from 307 applications in FY 2002 to 793 applications in FY 2006. FDA estimates it will receive 857 applications in FY 2008. These statistics demonstrate the urgent need for increased resources for the Generic Drug Review Program. The additional budget authority and proposed user fees in the Improving Generic Drug Review Initiative allow FDA to respond to the growing number applications.

Generic drugs often cost 20 to 70 percent less than their brand-name counterparts. The promise of significant savings makes timely review of generic drug applications a vital part of the Administration's strategy to reduce healthcare costs associated with prescription drugs.

The following table identifies the funding history for the Generic Drug Review Program and the FY 2008 levels, including the increased generic drug budget authority and proposed user fees:

Funding History for the Generic Drug Review Program

Program	FY 2006 Actuals	FY 2007 President Budget	FY 2008 Initiative	
			FY 2008 Total[1]	+/- 07 President Budget
Budget Authority				
Human Drugs	**$62,567,000**	**$64,600,000**	**$70,161,000**	**$5,561,000**
Center	$55,437,000	$58,000,000	$63,561,000	$5,561,000
Field	$7,130,000	$6,600,000	$6,600,000	-
User Fees				
Generic Drug User Fee	**0**	**0**	**$15,701,000**	**$15,701,000**
Program Total	**$62,567,000**	**$64,600,000**	**$85,862,000**	**$21,262,000**

[1] The FY 2008 Generic Drug total is $87,102,000. This includes generic drug funds and pay increase.

2. How does this initiative support important public health priorities?

This initiative supports the public health priorities of the HHS 500-day plan for Transforming Healthcare. Specifically, the initiative supports the Secretary's objective for rapidly approving safe new drugs, continually monitoring drug safety after approval, and proactively communicating new information to providers and patients. Improving generic drug review performance also supports other public health priorities:

- The initiative advances Medicare Rx objectives by promoting the availability of lower cost generic alternatives.

- The initiative advances Medicaid Modernization by enabling FDA to approve lower-cost generic drugs that generate savings to support a modernized Medicaid program.

- The initiative supports Pandemic Preparedness by allowing prompt review of generic drugs that support the HHS pandemic influenza response.

Furthermore, enhanced generic drug review ensures that American consumers have additional choices when buying drugs, which will produce a dramatic return on investment for the resources that FDA spends on generic drug review. The Congressional Budget Office estimates that generic drug use results in U.S. savings of $10 billion per year. One of the nation's largest pharmacy benefit management companies estimates that more extensive generic drug use could save an additional $20 billion per year. As $60-70 billion in brand name drugs lose patent protection in the next few years, Americans could substitute generic drugs for brand name drugs at a rate of 50 to 75 percent.

Enhanced generic drug review also directly supports the Secretary's vision for improving the human condition around the world. The FDA Generic Drug Review Program plays a significant role in the President's Emergency Plan for AIDS Relief (PEPFAR), by approving new generic treatments for HIV and AIDS. If FDA deems a generic drug safe and effective – but the brand name equivalent is still under patent in the United States – FDA can grant a tentative approval for the drug. The tentative approval allows the drug to be sold outside of the United States for HIV and AIDS treatment.

3. What are the risks of not funding this initiative?

Not proceeding with the Improving Generic Drug Review Initiative will result in the inability to capture significant savings from generic drug use. Generic drugs reduce the cost of pharmaceutical care and allow increased access to health care for many Americans. Generic drugs have the same quality, strength, purity, and stability as brand-name drugs.

Government programs rely on the availability of generic drugs to hold down costs. According to data from the National Association of Chain Drug Stores, in 2004 the average price of a brand prescription was approximately $96.01, while the average price of an available generic prescription was approximately $28.74. That is a difference of $67.27 per prescription.

Not funding this initiative limits the generic drugs available to treat diseases that are of major concern in the United States and abroad. The initiative also supports the availability of specialized drugs for foreign countries (under PEPFAR), and to assure availability of medical countermeasures to bioterrorism and natural disasters.

4. What activities will these funds support?

Budget Authority: The budget authority increase in the Improving Generic Drug Review Initiative directly supports core review functions in the Generic Drugs Program and allows CDER to sustain performance in a number of important areas:

- managing the existing generic drug application backlog as quickly and efficiently as possible
- increasing efficiency and improving generic drug review times by evaluating ways to improve communication with industry and improve the quality of applications
- assuring that generic drugs conform to manufacturing standards equal to the standard for brand name drugs
- providing medical and scientific expertise necessary to fulfill the President's commitment to ensuring the quality of HIV/AIDS drugs purchased by the United States for developing countries.

User Fees: The addition of fee resources under the Improving Generic Drug Review Initiative will allow FDA's Center for Drug Evaluation and Research (CDER) to ramp-up the Generic Drug program in FY 2008 and thereby begin to minimize the application backlog. CDER will hire staff to respond to the backlog. CDER will also enhance a range of operations, from establishing criteria for determining the bioequivalence of complex drugs and drugs with non-traditional dosage forms, to improving the information technology infrastructure that the generic drug program relies on to conduct application review.

Following the first full year of implementing this initiative, FDA will achieve a 50 percent increase in approvals. FDA currently performs an average of 40 approvals or tentative approvals per month. FDA will achieve the 50 percent increase after one full year because FDA must first hire and train the new generic drug review staff before it can achieve the additional approvals. During the next five years, the goal is to meet the statutory requirement for generic drug review by acting on 90 percent of original generic drug applications and amendments to unapproved applications within 180 days.

The funds in this initiative will support all activities associated with the review of generic drugs. FDA will achieve increased outputs from FY 2007 to FY 2008 in four measures:

- First cycle approvals will increase from two percent of applications approved or tentatively approved to five percent of applications approved or tentatively approved.
- FDA will reduce the time it takes to approve 40 percent of first generic applications without patent or exclusivity protection from 12 months to four months. FDA will also reduce the time it takes to approve 80 percent of first generic applications without patent protection from 14 months to six months.

This improvement depends on receiving the authority to formally expedite these applications.

- The number of domestic pre-approval generic drug inspections will increase from 110 to 155.
- The number of foreign pre-approval generic drug inspections will increase from 42 to 87.

5. What results will FDA achieve?

Budget Authority: With additional base resources for the Generics Drug Program, CDER will be able to approve or tentatively approve as many as 550 generic drugs per year. The American public will enjoy more cost saving from generic drugs.

User Fees: With the additional resources generated by the proposed Generic Drug User Fee, FDA will come closer to achieving generic drug review requirements. The statutory requirement for generic drug review is to act on original generic drug applications within 180 days. Currently, FDA estimates that performance toward this requirement with existing resources in FY 2006 and FY 2007 is near 55-60 percent percent. Although the number of generic drug applications that FDA receives will continue to rise, FDA expects that it can achieve the following performance toward meeting the statutory requirement:

- 70 percent by the end of FY 2008
- 72 percent by the end of FY 2009
- 73 percent by the end of FY 2010
- 75 percent by the end of FY 2011
- 80 percent by the end of FY 2012
- 85 percent by the end of FY 2013
- 90 percent by the end of FY 2014.