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August 21, 2003

Via fax and UPS

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003N-0084
Agency Information; Collection Activities; Submission for OMB Review; Comment Request; Electronic Records, Electronic Signatures – Part 11 (OMB Control No. 0910-0303) [Federal Register Volume 68, No. 141, page 43531-43532, July 23, 2003].

Dear Sir/Madam:

In response to the above referenced Docket No. 2003N-0084, we suggest that the burden created by the information collection provision of the 21 CFR Part 11 regulation is not limited to a "one-time" burden, but additionally includes an annual maintenance component. Further, the estimated annual reporting and record-keeping burden provided in Table 1 and Table 2 of the docket does not appear to adequately reflect the burden experienced by pharmaceutical firms such as Aventis.

For your consideration, we have included the following table, which summarizes Aventis' record-keeping experience with the 21 CFR Part 11 regulation and classifies the burden into *One-time* and *Annual Maintenance* activities.

Part 11 Section	Activity	No. of Organizational Units Impacted	No. of Computerized Systems	No. of FTEs Involved	No. of Records	Time Spent (hours)	One Time Burden (hours)	Annual Burden (hours)
11.100	P11 Certification	N/A	N/A	10	1	10	100	0
11.10	SOP Creation	30	N/A	2	10	40	24000	0
11.10	Annual SOP Review	30	N/A	3	10	2	0	1800
11.10	SOP Revision – 20% of Total SOPs	30	N/A	2	2	20	0	2400
11.10	Validation	N/A	1500	3	N/A	160	720000	
11.30	SOP Creation	30	N/A	2	1	40	2400	0

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Aventis Pharmaceuticals Inc. • 200 Crossing Boulevard • PO Box 6890 • Bridgewater, NJ 08807-0890 • www.aventis.com
Telephone (908) 304-7000

11.30	Annual SOP Review	30	N/A	3	1	2	0	180
11.50	SOP Creation	30	N/A	2	2	40	4800	0
11.50	Annual SOP Review	30	N/A	3	2	2	0	360
11.300	SOP Creation	30	N/A	2	2	40	4800	0
11.300	Annual SOP Review	30	N/A	3	2	2	0	360
11.30 11.50 11.300	SOP Revision – 20% of Total SOPs	30	N/A	2	1	20	0	1200
11.10 11.30 11.50 11.300	Part 11 Assessment and Compliance Strategy Definition for Existing	N/A	2500	3	2	4	60000	0
11.10 11.30 11.50 11.300	Part 11 Assessment for New Systems	N/A	400	3	1	4	0	4800
Total Burden							**816100**	**11100**

On behalf of Aventis Pharmaceuticals Inc., we greatly appreciate the opportunity to comment on Docket No. 2003N-0084 and hope that FDA will consider our input on the information collection burden created by the 21 CFR Part 11 regulation.

Sincerely,

Steve Caffé, M.D.
Vice President, Head US Regulatory Affairs

Sent via facsimile to: Fumie Yokota, Desk Officer
Office of Information and Regulatory Affairs, OMB
Fax No. (202) 395-6974