

1685 '03 AUG 25 410 38

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

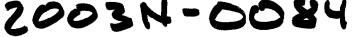
Agency Information; Collection Activities; Submission for OMB Review; Comment Request; Electronic Records, Electronic Signatures – Part 11 (OMB Control No. 0910-0303) [Federal Register Volume 68, No. 141, page 43531-43532, July 23, 2003].

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





| 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