

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per record	Total hours
111.15(b)(3) .....	231	12	2,772	0.1	277
111.15(d)(3) .....	231	260	60,060	0.25	15,015
111.25(d) .....	213	365	77,745	0.5	38,873
111.30(b)(2) and (b)(5) .....	707	260	183,820	0.5	91,910
111.35(d) .....	10	1	10	10	100
111.35(e) .....	367	260	95,420	0.25	23,855
111.35(f) .....	367	260	95,420	0.1	9,542
111.35(i)(1) .....	367	10	3,670	0.25	918
111.35(j) .....	367	260	95,420	.25	23,855
111.35(m) .....	367	365	133,955	0.1	13,396
111.37(b)(1), (b)(3) through (b)(5), (b)(7) through (b)(10), and (b)(12)(i) .....	286	260	74,360	0.5	37,180
111.37(c) .....	286	365	104,390	0.5	52,195
111.40(a)(3), (a)(4), (b)(2), and (b)(3) .....	449	365	163,885	0.1	16,389
111.40(c)(1) .....	218	365	79,570	0.5	39,785
111.45(a) <sup>2</sup> and (b) <sup>2</sup> .....	200	1	200	30	6,000
111.50(a) through (c), (d)(1), and (e) .....	68	260	17,680	1	17,680
111.50(g) .....	68	260	17,680	0.5	8,840
111.60(b)(2) .....	133	365	48,545	1	48,545
111.60(d) <sup>2</sup> .....	133	1	133	3	399
111.65(c)(7), (c)(10), and (c)(11) .....	133	365	48,545	0.1	4,855
111.70(b)(5) through (b)(6), (d), and (e) .....	245	260	63,700	0.1	6,370
111.70(g) .....	245	260	63,700	0.50	31,850
111.74(a) .....	200	12	2,400	0.1	240
111.82(a) .....	53	52	2,756	0.1	276
111.85(a) .....	53	260	13,780	0.1	1,378
111.85(d) and (e) .....	53	260	13,780	0.5	6,890
111.95(e) .....	53	75	3,975	0.1	398
111.95(f)(1) .....	93	75	6,975	0.5	3,488
111.125 .....	220	4	880	0.1	88
Total .....					500,587

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> One time burden.

The burden estimates above are based on our institutional experience with CGMP requirements for drugs and on data provided by Research Triangle Institute (RTI) in the "Survey of Manufacturing Practices in the Dietary Supplement Industry" (Refs. E1 and E2). We tentatively conclude that there are no capital costs or operating costs associated with this proposed rule. However, we invite comments on information provided in table 1 of this document or on any anticipated costs.

The estimates for number of firms affected by each provision of the rule are based on the percentage of manufacturers, ingredient suppliers, repacker/relabelers, distributors, and warehouseers that reported to RTI that they have not established or do not maintain records that would be required or recommended under the proposed rule. The RTI survey estimated that 1,566 firms would be covered by this rule including manufacturers, dietary ingredient suppliers, repacker/relabelers, distributors, and warehouseers. The time estimates include the burden involved in documenting that certain requirements

are performed and in recordkeeping. We used an estimated annual batch production of 260 batches per year to estimate the burden of requirements that are related to the number of batches produced annually, *e.g.*, proposed § 111.50, "What requirements apply to establishing a batch production record?" The estimate of 260 batches per year is near the midpoint of the number of annual batches reported by RTI survey firms.

Proposed § 111.125 prescribes the length of time for which CGMP records must be maintained. The burden chart reflects the estimated annual burden for record maintenance, for periodically reviewing records to determine if they may be discarded, and for any associated documentation for that activity for records that would be required under part 111. To avoid double-counting, we have not included a separate estimate of burden for those sections that would require maintaining records in accordance with proposed § 111.125, but have included a single burden estimate for all such records maintenance under proposed § 111.125. For example, proposed § 111.50(a)

would require that the batch production records be prepared every time a batch is manufactured and § 111.50(i) would require that batch production records be kept in accordance with proposed § 111.125. The estimated burden for establishing the batch production records is counted in proposed § 111.50(a) and the estimated burden for keeping the batch production records as would be required in accordance with § 111.50(i) is counted in proposed § 111.125.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted a copy of this proposed rule to OMB for its review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (*see ADDRESSES*).

## VI. Environmental Impact Considerations

The agency has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,