

TABLE 1.—REPORTING REQUIREMENTS—Continued

21 CFR Section	Reporting and Recordkeeping Requirements
203.39(e) 203.39(f)	Record of drug samples donated to a charitable institution. Records of donation and distribution or other disposition of donated drug samples.
203.39(g)	Inventory and reconciliation of drug samples donated to charitable institutions.
203.50(a)	Drug origin statement.
203.50(b)	Retention of drug origin statement for 3 years.
203.50(d)	List of authorized distributors of record.

The reporting and recordkeeping requirements are intended to help achieve the following goals:

1. To ban the reimportation of prescription drugs produced in the United States, except when reimported by the manufacturer or under FDA authorization for emergency medical care;

2. To ban the sale, purchase, or trade, or the offer to sell, purchase, or trade, of any drug sample;

3. To limit the distribution of drug samples to practitioners licensed or authorized to prescribe such drugs or to pharmacies of hospitals or other health care entities at the request of a licensed or authorized practitioner;

4. To require licensed or authorized practitioners to request samples in writing;

5. To mandate storage, handling, and recordkeeping requirements for drug samples;

6. To prohibit, with certain exceptions, the sale, purchase, or trade of, or the offer to sell, purchase, or trade, prescription drugs that were purchased by hospitals or other health care entities, or which were donated or supplied at a reduced price to a charitable organization;

7. To require unauthorized wholesale distributors to provide, prior to the wholesale distribution of a prescription drug to another wholesale distributor or

retail pharmacy, a statement identifying each prior sale, purchase, or trade of the drug.

In the **Federal Register** of December 2, 2002 (67 FR 71572), FDA requested comments on the proposed collection of information. FDA received one comment requesting that it be deemed an “other health care entity” and be permitted to receive and dispense samples to its patients. This comment does not pertain to the information collection estimates in the December 2, 2002, notice, and has been forwarded to the appropriate office in FDA that reviews these types of requests.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
203.11	12	1	12	.5	6
203.30(a)(1) and (b)	61,961	12	743,532	.06	44,612
203.30(a)(3), (a)(4), and (c)	61,961	12	743,532	.06	44,612
203.31(a)(1) and (b)	232,355	135	31,367,925	.04	1,254,717
203.31(a)(3), (a)(4) and (c)	232,355	135	31,367,925	.03	941,038
203.37(a)	25	1	25	6.00	150
203.37(b)	200	1	200	6.00	1,200
203.37(c)	50	1	50	1.00	50
203.37(d)	2,208	1	2,208	.08	177
203.38(a)	2,208	1	2,208	3.00	6,624
203.39(g)	3,221	1	3,221	2.00	6,442
203.50(a)	125	100	12,500	.08	1,000
Total Reporting Burden Hours					2,300,628

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
203.23(a) and (b)	31,676	5	158,380	.25	39,595
203.23(c)	31,676	5	158,380	.08	12,670
203.30(a)(2) and 203.31(a)(2)	2,208	100	220,800	.50	110,400
203.31(d)(1) and (d)(2)	2,208	1	2,208	40.00	88,320
203.31(d)(4)	442	1	442	24.00	10,608
203.31(e)	2,208	1	2,208	1.00	2,208
203.34	2,208	1	2,208	40.00	88,320
203.37(a)	25	1	25	18.00	450
203.37(b)	200	1	200	18.00	3,600
203.38(b)	2,208	14,543	32,111,457	.02	642,229
203.39(d)	65	1	65	1.00	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8.00	25,768