

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

21 CFR Section	No. of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
§ 201.25, § 610.67	1,447	31.1	45,000	24 hrs.	1,080,000
§ 314.81(b)(2)(iii)	1,447	5.9	8,576	10.5 min.	1,497
§ 601.12(f)(3)	211	1	211	1 min.	3.5
§ 606.121(c)(13)	981	42,507.7	41.7 million	1 min.	695,000
Total					1,776,590.5

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

Our estimates are based on the following assumptions.

- For prescription drugs (including prescription biologics and vaccines) and OTC drugs subject to the bar code requirement, information from our own records indicates that there are 1,447 establishments that would be affected by a bar code requirement, and there are approximately 89,800 separate, identifiable product packages subject to this proposed rule. We expect that half of the packages (45,000) would need redesigned labels to comply with a bar code requirement because they do not currently use coded NDC numbers. This means that the annual frequency of reports, under proposed § 201.25 (and proposed § 610.67 for biological products not regulated as devices), would be 31.1 (45,000 package labels requiring a bar code/1,447 establishments = 31.09 packages per establishment, which we have rounded up to 31.1). Consultations with industry sources suggest that the number of hours per response to redesign a package label to include bar coded information to comply with this regulation is approximately 24 hours. Therefore, the total burden hours for proposed § 201.25 and § 610.67 would be 1,080,000 hours (45,000 packages x 24 hours per package label = 1,080,000 hours).

- For prescription drugs whose label changes would be reported in an annual report under § 314.81 or under § 601.12(f)(3) for biological products), there are approximately 1,447 registered establishments that would be reporting. Information on listed drugs indicates there are 89,800 separate, identifiable product packages that will comply with the proposed bar code requirement. These packages account for 8,576 separate and distinct products (each product is marketed in an average of 10.47 packaging variations). This means that the annual frequency of reports would be 5.9 (8,576 products subject to annual reports/1,453 registered establishments = 5.92 products per registered establishment, which we have rounded down to 5.9). Section 314.81(b)(2)(iii) requires firms to submit

an annual report that includes a summary of any changes in labeling since the last annual report. Similarly, § 601.12(f)(3)(I)(A) requires manufacturers of biologics to include in their annual reports editorial or similar minor labeling changes. We expect that the addition of a bar code to a label would necessitate a simple statement in the annual report declaring that the bar code has been added, so we have assigned an estimate of one minute for such statements per label. Each product's annual report would include labels for all packaging variations. Thus, the total reporting burden would be 1,496.67 hours ((8,576 reports x 10.47 labels (or one label per packaging variation) per report x 1 minute per report)/60 minutes per hour = 1,496.67 hours), which we have rounded up to 1,497 hours.

- For minor labeling changes for blood and blood components included in an annual report under § 601.12(f)(3)(i)(A), FDA's database indicates there are 211 licensed blood and blood component manufacturers. We expect that the addition of machine-readable information to the label of blood and blood components would necessitate a simple statement in the annual report declaring that the machine-readable information has been added, so we have assigned an estimate of one minute for such statements. Thus, the total reporting burden would be 3.5 hours ((211 reports x 1 minute per report)/60 minutes per hour = 3.516 hours), which we have rounded down to 3.5 hours.

- For the requirement in proposed § 601.121(c)(13) to include machine-readable information on blood and blood components, FDA's registration database indicates there are 981 blood and plasma establishments. The American Association of Blood Banks estimates that approximately 13.9 million blood donations are collected annually. We estimate that each blood donation yields approximately three blood components. This means that the frequency of responses is approximately 41.7 million occurrences (13.9 million blood donations x three blood components per donation) divided by

981 establishments or 42,507.645 occurrences per establishment, which we have rounded up to 42,507.7. We estimate that it takes 1 minute to apply a machine-readable code manually; if a blood collection facility uses an on-demand printer, the time would range between 15 to 30 seconds. For purposes of this estimate, we adopt the larger time estimate of 1 minute per machine-readable information for blood, thus resulting in an annual reporting burden of 695,000 hours ((41.7 million reports x one minute per report) / 60 minutes per hour = 695,000 hours). However, we reiterate that facilities using on-demand printers would face lower burdens. In addition, blood collection centers are currently allowed and encouraged to apply machine readable information to collections. This burden estimate accounts for requiring an activity that is currently voluntary and does not reflect an additional activity.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to fax comments regarding information collection by April 14, 2003, to the Office of Information and Regulatory Affairs, OMB (see ADDRESSES).

## VI. Executive Order 13132: Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.